EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	**Case No.**
THIS DOCUMENT RELATES TO:	)	**Judge Dan Aaron Polster**
THE BOARD OF EDUCATION OF THE CITY OF CHICAGO, SCHOOL DISTRICT NO. 299 ("CHICAGO PUBLIC SCHOOLS"), on behalf of itself and others similarly situated,	)	
v.	)	**CLASS ACTION COMPLAINT**
CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., ORTH-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a/ JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, INC., INSYS THERAPEUTICS, INC., MALLINCKRODT, PLC, MALLINCKRODT LLC, ALLERGAN PLC f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a/ WATSON PHARMA, INC., AMERISOURCEBERGEN CORPORATION, CARDINAL HEALTH, INC., McKESSON CORPORATION, CVS HEALTH CORPORATION, WALGREENS BOOTS ALLIANCE, INC., A/K/A WALGREEN CO., and WALMART INC., F/K/A WAL-MART STORES, INC.,	)	
Defendants.	)	

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 2 of 214. PageID #: 2

TABLE OF CONTENTS

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 3 of 214. PageID #: 3

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 4 of 214. PageID #: 4

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 6 of 214. PageID #: 6

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 7 of 214. PageID #: 7

CLASS ACTION COMPLAINT AND JURY DEMAND

In accordance with 28 U.S.C. §1407 and Case Management Order One, *In Re: National Prescription Opiate Litig.*, No. 17-MD-2804, ¶ 6.a., Dkt. 232 (N.D. Oh. Apr. 11, 2018) (Polster, J.), this civil action is filed directly in this District for purposes of coordinated and consolidated pretrial proceedings.

I. INTRODUCTION.

1. The Board of Chicago School District No. 299 ("Chicago Public Schools", "CPS", or "Plaintiff") is the school district which provides all K-12 public education for the City of Chicago. Along with public school districts all over the country, CPS is experiencing unprecedented challenges and costs resulting from the impact of the nationwide opioid epidemic on its students and employees. As they have across the nation, opioids have become the main source of drug overdoses in Chicago, home to the students, teachers and other employees of CPS.

2. As a result of the impact of the opioid epidemic, CPS has incurred and continues to incur increased costs of the health services provided to its students and staff as well as the cost and burden of providing complex and expensive educational services to students who have suffered neurological damage *in utero* caused by opioid use by their mothers during pregnancy.

3. The opioid crisis has had a particularly profound impact on women, who are more likely than men to suffer from chronic pain, receive prescriptions for pain relievers and in higher doses, and use them for longer periods of time.[1] Women may become more dependent on prescription pain relievers more quickly than men.[2] Prescription pain reliever overdose deaths

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[1] *Opioid Addiction 2016 Facts & Figures*, American Society of Addiction Medicine, https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.
[2] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 8 of 214. PageID #: 8

among women increased more than 400% from 1999 to 2010, compared to 237% among men.[3] The rates of Neonatal Abstinence Syndrome (NAS), which occurs when a baby is born addicted to opioids as a result of use by the mother during pregnancy, have also increased dramatically.[4] Nationally, the cost of treating NAS increased from $61 million in 2003 to nearly $316 million in 2012.[5]

4. CPS brings this action on behalf of itself and (1) a national class of all public school districts which are independent units of government and (2) a sub-class of all public school districts in the State of Illinois[6] (jointly referred to unless otherwise specified as "the Class"). Plaintiff and the Class bear the steadily rising costs of providing health care to their staff as a result of opioid addiction related conditions as well as special education and related services to children who were exposed to opioid use *in utero*, making them twice as likely to exhibit learning and developmental disabilities than children who were not exposed.[7] Not surprisingly, Plaintiff and the Class have seen a rise in the number of children entering school with special education needs as a result of the rise in the nationwide rates of NAS.[8]

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[3] *Id.*

[4] Hannah Rappleye et al., *Born Addicted: The Number of Opioid-Addicted Babies is Soaring*, NBC News, Oct. 9, 2017, https://www.nbcnews.com/storyline/americas-heroin-epidemic/born-addicted-number-opioid-addicted-babies-soaring-n806346. *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last updated Sept. 2015).

[5] T.E. Corr & C.S. Hollenbeak, *The economic burden of neonatal abstinence syndrome in the United States*, 112 Addiction 1590 (Sept. 2017), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13842.

[6] All of the public school districts in the State of Illinois are independent units of government, rather than agencies or sub-units of municipalities, counties, states or other units of government.

[7] Paul Morgan and Yangyang Wang, *The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services*, 25 American Journal of Managed Care 13 (2019).

[8] Chicago Public Schools, School Data, Demographics, https://cps.edu/SchoolData/Pages/SchoolData.aspx.

5. Plaintiff and members of the Class bear the cost of their workers' health insurance plans, including prescription drugs and addiction treatments, as well as workers' compensation. As a result, Plaintiff and the Class have for many years footed the bill for their workers' increased use of prescription opioids, and the treatments required as a result of their workers' opioid addictions, including treatment for overdoses and leaves of absences.

6. Plaintiff and members of the proposed Class are frequently the first to identify a student in crisis, and the first point of contact for students who need support in the face of crisis. As a result, they have born costs for increased use of prescription opioids among students, including by providing resources to teachers and administrators who are on the front lines helping students, and by providing specialized health and/or counseling programs for opioid-addicted students. Even if the opioid crisis is abated today, the costs that Plaintiffs and members of the proposed Class will incur increase exponentially in the years to come as the current cohort of adversely impacted children advance from lower school to high school with special needs all along the way.

7. Public health officials have called the current opioid epidemic the worst drug crisis in American history.[9] On October 26, 2017, the President of the United States declared it a public health emergency. That year, opioid overdoses were responsible for more than 47,000 American deaths, and around 1.7 million people suffered from addiction related to prescription opioids.[10] According to recent estimates, as many as 130 people in the United States die every

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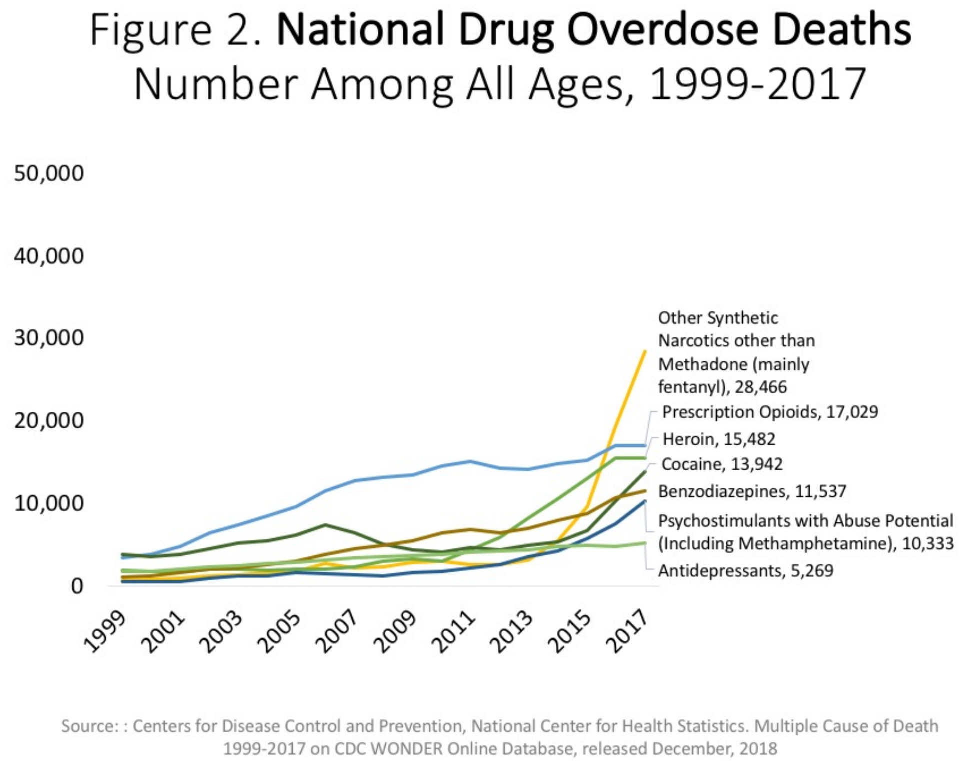
[9] Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.
[10] *Opioid Overdose Crisis*, NIH: National Institute on Drug Abuse (Jan. 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 10 of 214. PageID #: 10

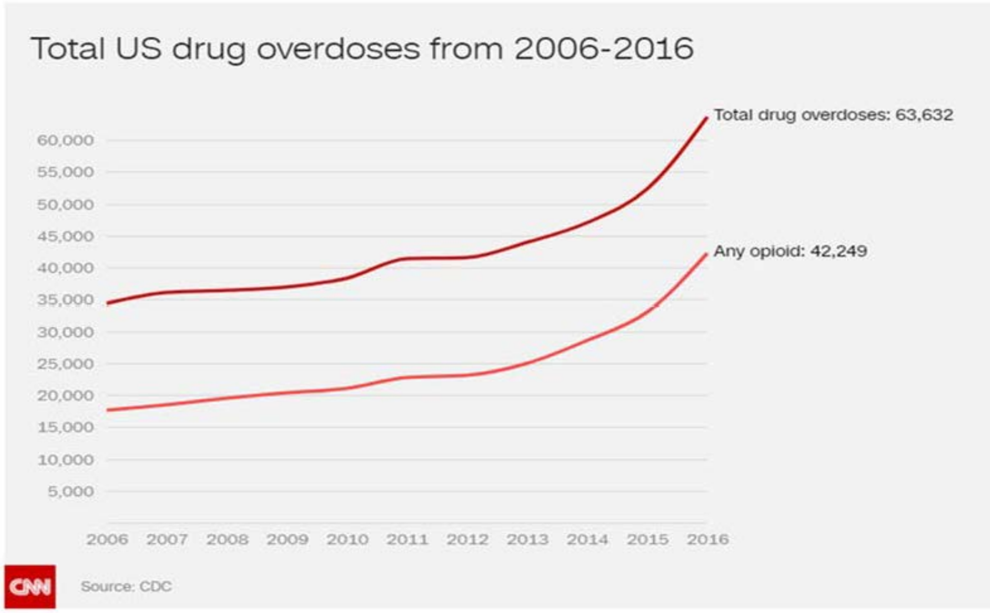
day from opioid overdoses, with as many as 35 percent of fatal overdoses involving prescription opioids.[11]

8. The following charts illustrate the rise of opioid-related overdose deaths in the United States:[12]



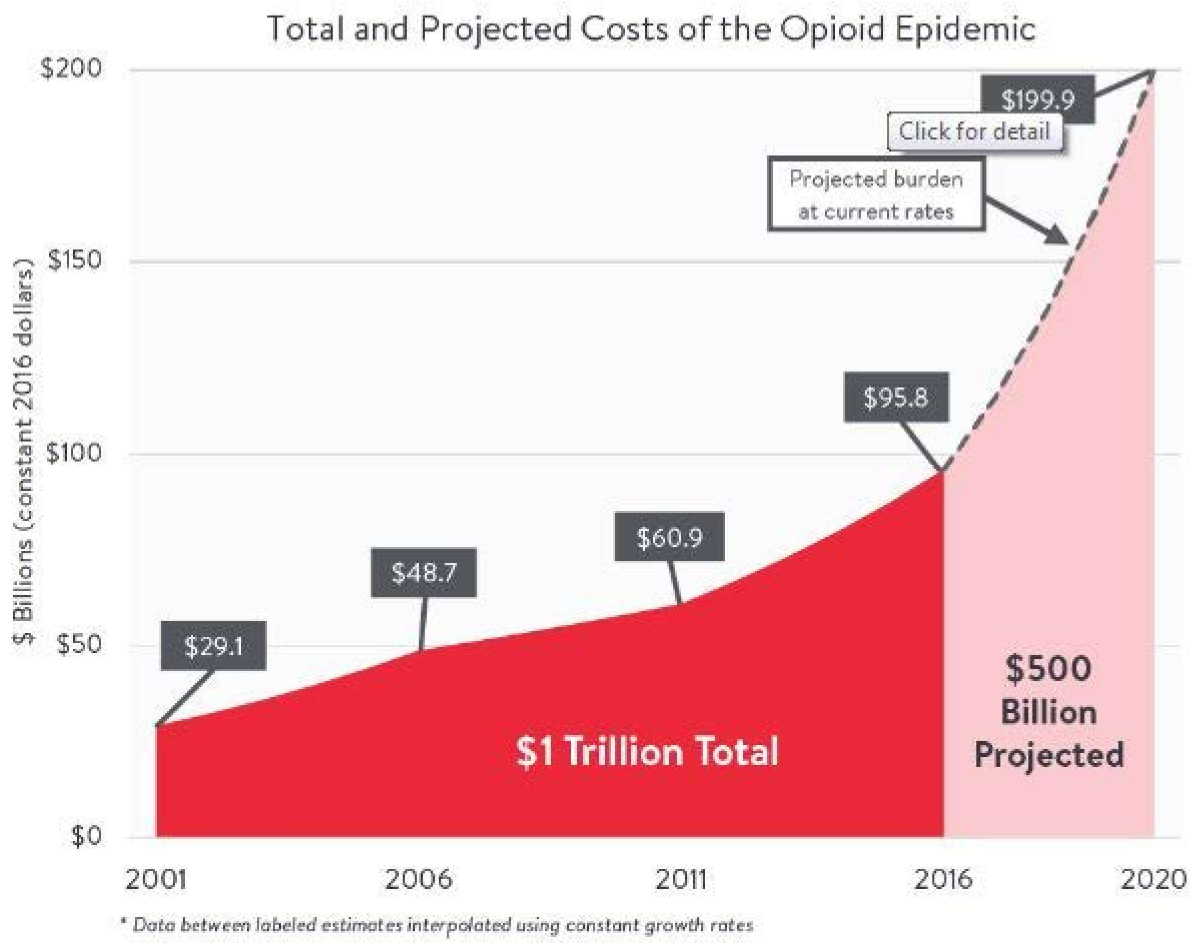
[11] *Id.* Overdose Deaths Involving Prescription Opioids, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html (last visited Sept. 19, 2019).

[12] *Overdose Death Rates*, National Institute of Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (hereinafter, "*Overdose Death Rates*") (last visited Dec. 14, 2018). *Opioids now kill more people than breast cancer*, CNN (Dec. 21, 2017), https://wtvr.com/2017/12/21/opioids-now-kill-more-people-than-breast-cancer/.

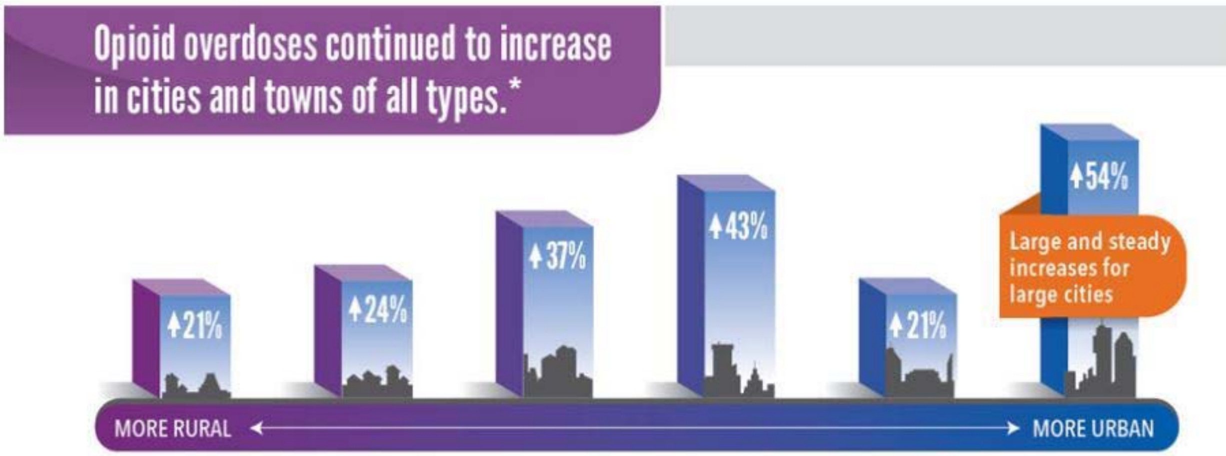


9. The opioid crisis and related expenses continue to grow. According to a report issued on February 13, 2018 by Altarum, a nonprofit health systems research and consulting organization, the cost of the country's opioid crisis is estimated to have exceeded $1 trillion from 2001 to 2017, and is projected to cost an additional $500 billion by 2020:[13]

[13] *Economic Toll Of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, Altarum (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001.



10. According to a Centers for Disease Control and Prevention ("CDC") report issued in March 2018, hospital emergency room visits for opioid overdoses rose 30% nationwide between July 2016 and September 2017. Over the same period, emergency room visits for opioid overdoses in large cities increased by 54%:



SOURCE: CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) Program, 16 states reporting percent changes from July 2016 through September 2017.

* From left to right, the categories are:
1) non-core (non-metro), 2) micropolitan (non-metro), 3) small metro, 4) medium metro, 5) large fringe metro, 6) large central metro.

11. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is one of the main drivers of the opioid epidemic. Prescription opioids are powerful pain medications that historically have been used for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are highly addictive and dangerous, the U.S. Food and Drug Administration ("FDA") regulates them as Schedule II Controlled Substances, *i.e.*, drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

12. This demonstrated need for caution comports with the historical understanding of both the medical community and American culture at large regarding the serious consequences of opioid use and misuse. Opioids powerful ability to relieve pain comes at a steep price; opioids are dangerously addictive and often lethal substances. For generations, physicians were taught that opioid painkillers were highly addictive and should be used sparingly and primarily for patients near death.[14] The medical community also understood that opioids were poorly suited

[14] Harriet Ryan et al., *OxyContin goes global – "We're only just getting started,"* L.A. Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter, "Ryan, *OxyContin goes global*").

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 14 of 214. PageID #: 14

for long-term use because tolerance would require escalating doses and dependence would make it extremely difficult to discontinue their use.

13. The prevailing and accurate understanding of the enormous risks and limited benefits of long-term opioid use constrained drug manufacturers' ability to drive sales. In order to decrease reasonable concerns about opioids and to maximize profits, opioid manufacturers, including defendants[15] Sackler and Purdue Co-Conspirators (defined below in § II (C)), Janssen, Endo, Cephalon, Insys, Mallinckrodt and Actavis (individually defined in § II (B)) (collectively, the "Manufacturing Defendants") engaged in a concerted, coordinated strategy to shift the way in which doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from such things as acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic pain conditions.

14. Borrowing from the tobacco industry's playbook, the Manufacturing Defendants employed ingenious marketing strategies, as detailed further herein, designed to "reeducate" the public and prescribers. The Manufacturing Defendants deliberately conceived these strategies to create, and in fact did create, an entirely new "health care" narrative – one in which opioids are considered safe and effective for long-term use, and pain is aggressively treated at all costs. According to this newly fabricated narrative, pain was seriously under treated throughout the United States because opioids were under prescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids.

15. The Manufacturing Defendants' intention was to normalize aggressive prescribing of opioids for various kinds of pain by downplaying the very real and serious risks of opioids,

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[15] The Purdue Pharma entities are not listed as defendants at this time because they recently filed for bankruptcy.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 15 of 214. PageID #: 15

especially the risk of addiction, and by exaggerating the benefits of use. To accomplish this goal, they intentionally misled doctors and patients about the appropriate uses, risks, safety and efficacy of prescription opioids. They did so directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, hospitals, trade associations for state medical boards and seemingly neutral third-party foundations.

16. False messages about the safety, addictiveness and efficacy were disseminated by infiltrating professional medical societies and crafting and influencing industry guidelines in order to disseminate false and deceptive pro-opioid communiques under the guise of science and truth. According to a February 2018 report issued by U.S. Senator Claire McCaskill, opioid manufacturers, including several of the Manufacturing Defendants, paid nearly $9 million between 2012 and 2017 to advocacy groups and professional societies operating in the area of opioids policy.[16] The manufacturers got their money's worth:

> Initiatives ***from the groups in this report often echoed and amplified messages favorable to increased opioid use*** – and ultimately, the financial interests of opioid manufacturers. ***These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids*** for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding.[17]

17. The purportedly neutral medical societies also "strongly criticized 2016 guidelines from the . . . (CDC) that recommended limits on opioid prescriptions for chronic

[16] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (Feb. 13, 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (hereinafter, "*February 2018 McCaskill Report*").
[17] Emphasis is added throughout unless otherwise noted.

pain," which the *February 2018 McCaskill Report* described as "a key federal response to the ongoing epidemic." In conclusion, the report found "a direct link between corporate donations and the advancement of opioids-friendly messaging."

18. The Manufacturing Defendants falsely assured the public and prescribers that the risk of becoming addicted to prescription opioids among patients being treated for pain was less than 1%. In reality, many people with no addiction history can become addicted after just weeks or even days of use.[18] According to estimates, as many as 56% of patients receiving long-term prescription opioid painkillers become addicted.[19] Indeed, almost one in five people who receive an opioid prescription with ten days' supply will still be taking opioids one year later.[20]

19. The Manufacturing Defendants' focus on driving opioid sales growth led to concomitant growth in the number of deaths resulting from opioid use and in hospital admissions for opioid-related addiction treatment:[21]

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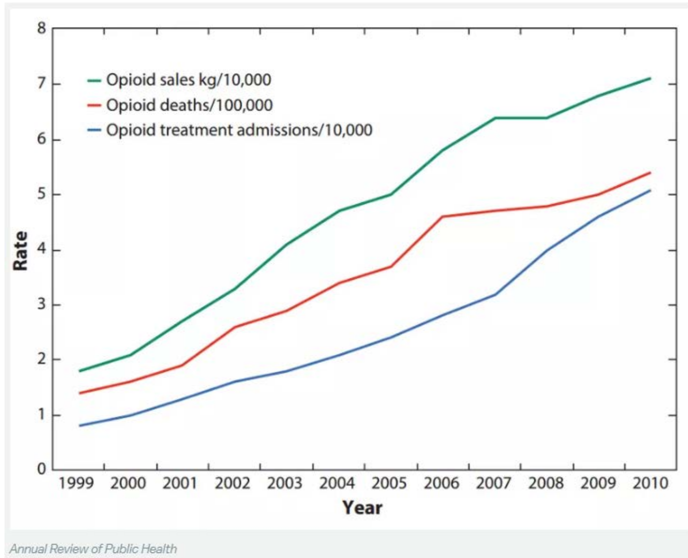
[18] Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, 22 (Johns Hopkins University Press 2016) (hereinafter, "Lembke (2016)").
[19] Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-painprevalence-efficacy-association (hereinafter, "Martell, *Systematic Review*").
[20] Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 20107, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioidoveruse-prescribe-them-for-3-days-or-less.
[21] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Annu. Rev. Public Health 559-74 (2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.



20. Put simply, the Manufacturing Defendants manipulated and misrepresented medical science to increase sales and profits at great human cost. Indeed, in a study published on March 6, 2018 in the *Journal of the American Medical Association* ("*JAMA*"),[22] researchers who conducted the first randomized clinical trial designed to compare the efficacy of opioids and non-opioids (including acetaminophen, ibuprofen and lidocaine) for the treatment of moderate to severe back pain, hip pain or knee osteoarthritis pain concluded that patients who took opioids over the long term experienced improvements in pain-related function no better than patients who used safer alternatives.

21. Defendants McKesson, Cardinal Health and AmerisourceBergen (individually defined in § II (D)) (collectively, the "Distributor Defendants") are major distributors of controlled substances that act as middlemen between drug companies and pharmacies. Like the Manufacturing Defendants, the Distributor Defendants were also aware of a growing epidemic

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[22] Erin E. Krebs et al., *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, The SPACE *Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, "Krebs, *Effect of Opioid vs. Nonopioid Medications*").

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 18 of 214. PageID #: 18

arising from the addiction to, and abuse of, prescription opioids they supplied. The Manufacturing Defendants and the Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed nationwide, including to entities in Chicago and elsewhere in Illinois. However, both the Manufacturing Defendants and the Distributor Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to rising addiction and overdose rates nationwide, including in Chicago and elsewhere in Illinois.

22. Recently released data on the sale of prescription pain pills shows the full extent of Defendants' scheme to saturate the market with opioid medications. The Drug Enforcement Administration (DEA) tracks the manufacturing and distribution of oxycodone and hydrocodone pills, which represent 75% of all opioid pill shipments distributed to pharmacies.[23] Between 2006 and 2012, over 1.9 billion oxycodone and hydrocodone pills were distributed in Illinois. Distributor Defendants McKesson Corporation and Cardinal Health were two of the top five distributors of prescription pain pills in the state, and Marketing Defendant Actavis Pharma was the top manufacturer of pills in the state, with Purdue Pharma, also in the top 5.[24]

23. Distributor Defendants McKesson, Cardinal Health, and AmerisourceBergen were key players in the spread of opioid pain relievers, responsible for 44% of the country's supply of prescription pain pills. Similarly, Marketing Defendant Actavis Pharma manufactured 34.5% of the opioids distributed nationwide, and Purdue Pharma was responsible for an additional 3.3% of the market during the years recorded.

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[23] The following statistics are available through the *Washington Post*'s interactive DEA pain pill database. *Drilling into the DEA's pain pill database,* The Washington Post (Updated July 21, 2019), https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/.
[24] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 19 of 214. PageID #: 19

24. The production and distribution of massive quantities of prescription pain pills was not an accident. Defendants' decision to ignore red flags, and their consistent failure to report suspicious orders, resulted in a market flooded with prescription opioids. From 2006 to 2012, the volume of opioid pills handled by the 10 largest companies increased by 51%. During this time there were 36 opioid pills for every person in the country, and nationwide sales of prescription opioid pain pills increased from $6.1 billion to $8.5 billion over the six-year period.[25]

25. The country's major opioid distributors have paid hefty fines for their failure to report suspicious orders of opioids as required by law. McKesson, the largest prescription drug wholesale company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government. In December 2016, Cardinal Health reached a $44 million settlement with the federal government. One month later, Cardinal Health reached a $20 million settlement with the State of West Virginia. AmerisourceBergen also agreed to pay West Virginia $16 million in 2017.[26] As of 2019, corporations have paid almost $500 million in fines to the Justice Department, for "failing to report and prevent suspicious [opioid] drug orders."[27]

26. Defendants' scheme was tremendously successful if measured by profit. According to *Fortune* magazine, McKesson, AmerisourceBergen and Cardinal Health are each

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[25] Scott Higham et al., *76 billion opioid pills: Newly released federal data unmasks the epidemic*, The Washington Post (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html (hereinafter, "Higham et al., *76 billion opioid pills*").
[26] Nate Raymond, *McKesson to pay $37 million to resolve West Virginia opioid lawsuit*, Reuters (May 2, 2019), https://www.reuters.com/article/us-usa-opioids-litigation/mckesson-to-pay-37-million-to-resolve-west-virginia-opioid-lawsuit-idUSKCN1S81HO; Press Release, U.S. Department of Justice, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[27] Higham et al., *76 billion opioid pills*, *supra* n.25.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 20 of 214. PageID #: 20

among the top 15 companies in the Fortune 500. The Sackler family[28] owns Purdue Pharma, LP – a privately held company which would be named as a defendant herein were it not for the automatic stay triggered by its recent bankruptcy filing. The Sackler family is listed on *Fortune*'s list of America's wealthiest families. The Sacklers caused Purdue to engage in "ruthless marketing of painkillers has generated billions of dollars – and millions of addicts."[29]

27. The impact of opioid addiction has devastated the nation, emerging as one of the major health threats in Chicago, in Illinois and throughout the nation. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein, that "mistake" was not a mistake at all. Instead, it directly resulted in large part from defendants' false and misleading messaging, which was carefully calculated to reach as many prescribers as possible, as well as defendants' willingness to turn a blind eye to suspicious orders.

28. Even when some defendants were forced to admit the unlawful marketing and sale of opioids and/or the failure to report suspicious orders, the conduct did not abate because profits realized by the aggressive marketing and prescribing of opioids dwarf the penalties imposed as a result of violations found. The fines were absorbed as part of the overhead for engaging in this lawless and immoral behavior as the incentive to push opioids remained. The scheme was so financially successful, in fact, that despite the clear and obvious devastation it caused in the U.S., Purdue's owners, the Sacklers, continue to pursue the same strategy abroad.

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[28] Including co-conspirators RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, BEVERLY SACKLER, THERESA SACKLER, DAVID A. SACKLER, TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY (collectively, "the Sacklers").

[29] Patrick Radden Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, Empire of Pain"), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 21 of 214. PageID #: 21

As reported by the *Los Angeles Times* in 2016, Purdue stated "[w]e're only just getting started," and intends to "[p]ut the painkiller that set off the United States opioid crisis into medicine cabinets around the world. A network of international companies owned by the family is moving rapidly into Latin America, Asia, the Middle East, Africa and other regions, and pushing for broad use of painkillers in places ill-prepared to deal with the ravages of opioid abuse and addiction."[30]

29. While great attention has been paid to the strain placed on states and local governments for their vast public health expenditure relating to the opioid epidemic, the astounding harm caused to our nation's public schools has gone largely unnoticed. Children born with opioid exposure in utero are the most blameless and tragic victims of the opioid epidemic, and they suffer from a host of developmental and behavioral problems for the rest of their lives. Public schools are tasked with finding the resources to provide special support and education to these children.

30. In addition, public schools are the country's largest public employer, and they provide health insurance and other benefits to their employees. Thus, public schools have footed the bills for employees' prescription opioids—including those prescribed inappropriately—and for the resulting healthcare costs, including addiction treatment and workers' compensation.

II. PARTIES.

A. Plaintiff.

31. Plaintiff, Chicago School District No. 299 ("Chicago Public Schools" or "CPS"), brings this civil action against Defendants on behalf of itself and other similarly-situated independent public school districts for operating a continuous criminal enterprise in violation of

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[30] Ryan, *OxyContin goes global*, *supra* n.14.

federal and state law, and to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate its nuisance, and to recoup monies spent because of Defendants' false, deceptive, and/or unfair marketing and unlawful distribution of dangerous prescription opioids.

32. Chicago Public Schools is the third largest school district in the nation. CPS is a political subdivision of the State of Illinois, formed for the purpose of administrating the public school system in Chicago. With an annual budget of $5.8 billion, CPS serves approximately 360,000 students and operates more than 600 educational facilities, including alternative educational facilities. It provides medical insurance coverage, workers' compensation, and long-term disability insurance to its 37,000 employees.

33. CPS serves a large low-income student population. As of June 2019, 77 percent of CPS students qualify for Medicaid. As of 2018, 82 percent of CPS students qualified for free or reduced lunch and approximately 4 percent of CPS's student population, or about 15,000 students are homeless.

34. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which Plaintiff seeks relief. Categories of past and continuing sustained damages include, but are not limited to: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for covered patients suffering from opioid-related addiction or disease, including overdoses; (2) costs associated with increased healthcare and healthcare insurance; (3) costs regarding disability payments; (4) costs associated with special education provisions, including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling due to opioid-related family crisis; (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; and (6)

costs associated with increased school security in all facilities of the school board district. These damages have been suffered and continue to be suffered directly by Plaintiff and are trebled as a matter of law.

35. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct. Plaintiff is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance.

B. "Manufacturing Defendants."

36. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania. Cephalon, Inc. was acquired by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") in October 2011. Teva Ltd. is incorporated under the laws of Israel with its principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon, Inc., its United States sales and marketing activities have been conducted by defendant Teva Pharmaceuticals USA, Inc. ("Teva USA" and, together with Teva Ltd., "Teva"), a wholly owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Cephalon, Inc. and Teva are collectively referred to herein as "Cephalon."

37. Defendant Endo International plc is an Irish public limited company with its headquarters in Dublin, Ireland. Defendant Endo Health Solutions Inc. is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals Inc. (together with Endo International plc and Endo Health Solutions Inc., "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly, wholly owned subsidiary of Endo International plc.

38. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.). Janssen is a Pennsylvania corporation headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

39. Defendant Johnson & Johnson, Inc. is a New Jersey corporation that is headquartered in New Brunswick, New Jersey.

40. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

41. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Defendant Mallinckrodt LLC (together with Mallinckrodt plc, "Mallinckrodt") is a Delaware limited liability company with its headquarters in Hazelwood, Missouri.

42. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in 2015, and the combined company changed its name to Allergan plc. Defendant Actavis, Inc. was acquired by Defendant Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, then to Actavis plc in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of

business in Parsippany, New Jersey. Each of these defendants and entities is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, the defendants and entities in this paragraph are referred to as "Actavis."

C. "Distributor Defendants."

43. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania.

44. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its headquarters and principal place of business located in Dublin, Ohio.

45. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California.

1. "National Retail Pharmacies"

46. Defendant CVS Health Corporation ("CVS") is a Delaware Corporation with its principal place of business in Rhode Island. CVS, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Illinois and Chicago specifically.

47. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. Walgreens, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a license wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Illinois and Chicago.

48. Defendant Walmart Inc. ("Walmart"), formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Illinois and Chicago.

49. Collectively, CVS, Walgreens, and Walmart are referred to as "National Retail Pharmacies" and/or "Distributor Defendants."

D. Unnamed Co-Conspirators.

50. Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P. and Purdue Products L.P. Rhodes Pharmaceuticals L.P. ("Rhodes") is a Delaware limited partnership formed in or around 2007 with headquarters located in Coventry, Rhode Island. Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., Purdue Products L.P. and Rhodes are referred to collectively herein as "Purdue." Purdue recently filed for bankruptcy and therefore is not named as a Defendant at this time.

51. Richard S. Sackler is a natural person residing in Travis County, Texas. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

52. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 27 of 214. PageID #: 27

53. Mortimer D.A. Sackler is a natural person residing in New York County, New York. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

54. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

55. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She served as a member of the Board of Directors of Purdue and Purdue-related entities since from the 1990s until approximately 2017-2019.

56. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

57. Theresa Sackler is a natural person residing in New York County, New York. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

58. David A. Sackler is a natural person residing in New York County, New York. He served as a member of the Board of Directors of Purdue and Purdue-related entities from 2012 until approximately 2018.

59. Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust for which Beverly Sackler, Richard S. Sackler and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities. Collectively, the co-conspirators listed in ¶¶ 51-59 are referred to as the

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 28 of 214. PageID #: 28

"Sacklers." On October 11, 2019, U.S. Bankruptcy Judge Robert Drain, presiding over in *In re: Purdue Pharma, L.P., et al*., 19-23649 (Bankr. S.D.N.Y.), ordered a temporary halt to litigation against the Sacklers until at least November 6, 2019. The court then extended that halt until at least April 8, 2020. Therefore, the Sacklers are not named as Defendants at this time.

III. JURISDICTION AND VENUE.

60. This Court has jurisdiction over Plaintiffs' claims for the purposes of pretrial proceedings pursuant to 28 U.S.C. §1407.[31]

61. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, based on Defendants' violations of federal law, specifically 18 U.S.C. § 1961, *et seq.* ("Racketeer Influenced and Corrupt Organizations Act" or "RICO"), 18 U.S.C. § 1965 pertaining to RICO jurisdiction, and supplemental jurisdiction over the state law claims set forth below pursuant to 28 § 1367, because those state law claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

62. The U.S. District Court for the Northern District of Illinois has personal jurisdiction over Defendants, because they conduct business in Illinois, purposefully direct or directed their actions toward Illinois, and have the requisite minimum contacts with Illinois necessary to constitutionally permit this Court to exercise jurisdiction. That Court also has personal jurisdiction over all Defendants under 18 U.S.C. 1965(b). That Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service, and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a

[31] *See* Case Management Order One, ¶ 6.a., Dkt. 232 ("In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal districts, any Plaintiff whose case would be subject to transfer to these MDL proceedings may file its case directly in this District").

single trial. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within the State of Illinois, the damages were sustained by Plaintiff and the Illinois Class within the State of Illinois, and the damages sustained by Plaintiff and the Class were a result of Defendants' actions and/or inactions— described herein—that were purposefully directed at and/or within the State of Illinois.

63. Venue in the Northern District of Illinois is proper, as various Defendants herein are registered to do business in the judicial district in which this matter is filed, may be served in this judicial district, conduct the business activities described herein in this judicial district, and various actions and/or inactions sued upon occurred in this judicial district. 18 U.S.C. § 1965(a); 28 U.S.C. §1391(b)(2).

IV. FACTUAL ALLEGATIONS.

A. Prescription Opioids.

64. The term opioid refers to (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone oxycodone and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.

65. Opioids are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the federal government as controlled substances.

66. Since passage of the Controlled Substances Act ("CSA") in 1970, 21 U.S.C. § 801, *et seq*., controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest[32]. Opioids generally had been categorized

[32] Schedule I drugs are defined by the CSA as drugs with no currently accepted medical use and a high potential for abuse.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 30 of 214. PageID #: 30

as Schedule II or Schedule III drugs. Schedule II drugs have "a high potential for abuse," have "a currently accepted medical use," and "may lead to severe psychological or physical dependence."[33] Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA.[34] The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.[35]

67. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are "frighteningly high."[36] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels. These risks do not provide attendant rewards. Studies on opioid use have demonstrated a correlation between high opioid dosage and poor physical function, as well as worsened overall general health.[37] Opioid use also delays injury recovery and increases the risk of permanent disability. In a study of Workers Compensation claims for lower back pain, increasing a patient's opioid dosage was found to correlate with an increasing risk of disability

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[33] 21 U.S.C. § 812(b)(2).
[34] 21 U.S.C. § 829.
[35] *See, e.g.*, March 22, 2016, Required Safety Labeling Language for Immediate Release Opioids, FDA, https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM491594.pdf.
[36] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010).
[37] Kathryn Sullivan Dillie, et al., Quality of Life Associated With Daily Opioid Therapy in a Primary Care Chronic Pain Sample, 21 J. of the Am. Bd. Of Fam. Med. 108 (2008).

compared to non-opioid users.[38] Another study showed that prescribing opioids within six weeks of an injury actually *doubled* the risks of disability one year later.[39] Likewise, studies on opioid use prior to back surgery show poorer outcomes for patients including increased pain, decreased function, and increased depression.[40]

68. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, all of which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

69. During much of the latter half of the 20th century, doctors used opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during and immediately after surgery, or for palliative cancer or end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Doctors' reluctance to use opioids for an extended period was due to the legitimate fear of causing addiction.

70. Beginning in the late 20th century, however, and continuing through today, the Defendants acted to dramatically expand the marketplace for opioids. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief.

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[38] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016) (citing Barbara S. Webster, et al., *Relationship Between Early Opioid Prescribing for Acute Occupation Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery, and Late Opioid Use*, 32 Spine 2127 (Sept. 2007)).
[39] Teater, *supra* n.38, (citing Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: the Disability Risk Identtification Study Cohort*, 33 Spine 199 (2008)).
[40] Teater, *supra* n.38, (citing Sheyan J. Armaghani, et al., *Preoperative Opioid Use as a Predictor of Adverse Postoperative Self-Reported Outcomes in Patients Undergoing Spine Surgery*, 96 J. Bone & Joint Surgery (American) e89 (2014)).

Defendants recognized that if they could sell opioids, not just for short-term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and dramatically increase their profits. They further recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

B. Over the Course of More Than Two Decades, the Manufacturing Defendants Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates to Soar.

71. From the mid-90s to the present, the Manufacturing Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, they knew it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis that has ravaged the nation.

1. Background on Opioid Overprescribing.

72. The Manufacturing Defendants' scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called "evidence." First was the publication of a 5-sentence, 100-word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[41]

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[41] This very brief Letter to the Editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"), reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980). However, the letter did not support the conclusion that opioids were safe for long-term treatment of chronic pain, the conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter was used to launch the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 (hereinafter, "Jacobs, *One-paragraph letter*"). As discussed in a 2009 article in the *American*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 33 of 214. PageID #: 33

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[42]

73. Second was a single medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[43] Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use, who essentially made it his life's work to campaign for the movement to increase use of prescription opioids. He was one of Big Pharma's[44] "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by the Manufacturing Defendants and organizations paid by them as continuing medical education ("CME") programs

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Journal of Public Health, the 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, *Promotion and Marketing*").

[42] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioidepidemic- letter-1980-study.

[43] In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None were. *See* Lembke (2016), supra n.18 at 59-62.

[44] "Big Pharma" is used herein to refer to large pharmaceutical companies, including, but not limited to, defendants, considered especially as a politically influential group.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 34 of 214. PageID #: 34

for doctors. Portenoy was a paid propagandist for Big Pharma who had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[45]

74. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis noted the important and detrimental role played by the 1980 Letter to the Editor and the Portenoy Publication, in a section of the Commission's Report with the header "Contributors to the Current Crisis.".[46]

75. Portenoy has now admitted that he intentionally minimized the risks of opioids.[47] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. ***In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind***.[48]

76. The damage, however, was already done. The Manufacturing Defendants used these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the

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[45] Lembke (2016), *supra* n.18, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).
[46] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[47] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter, "Gounder, *Who Is Responsible*").
[48] Jacobs, *One-paragraph letter, supra* n.59; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 35 of 214. PageID #: 35

foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioid therapy. By 1997, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturing Defendants) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of addiction or overdose in pain patients.[49]

77. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturing Defendants introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and OxyContin in 1995, Janssen introduced Duragesic in 1990 and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana and Opana ER were approved by the FDA in 2006, as was Janssen's Nucynta in 2008 and Nucynta ER in 2011, Cephalon's Fentora in 2006 and Insys' Subsys in 2012.

78. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

79. Despite the prescription opioids' highly addictive qualities, the Manufacturing Defendants launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term

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[49] Jacobs, *One-paragraph letter, supra* n.41.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 36 of 214. PageID #: 36

pain and everyday use. Contrary to what doctors had previously understood about opioid risks and benefits, they were encouraged for the last two decades by the Manufacturing Defendants to prescribe opioids aggressively, and were assured, based on false evidence provided directly by the Manufacturing Defendants and numerous medical entities funded by the Manufacturing Defendants and others with financial interests in generating more opioid prescriptions, that: (a) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even as low as less than 1%; and (b) great harm was caused by "undertreated pain." These two foundational falsehoods led directly to the current opioid crisis.

80. The strategy was a striking marketing success. It was designed to redefine back pain, neck pain, headaches, arthritis, fibromyalgia and other common conditions suffered by most of the population at some point in their lives as a single malady – chronic pain – that doctors and patients should take seriously and for which opioids were an appropriate, successful and low-risk treatment. Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer pain.[50]

81. This false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[51]

82. Thus, based on false and incomplete evidence, the Manufacturing Defendants expanded their market exponentially from patients with end-stage cancer and acute pain, an obviously limited customer base, to anyone suffering from chronic pain, which by some accounts

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[50] Ryan, *OxyContin goes global*, *supra* n.14.
[51] Lembke (2016), *supra* n.18, at 22 (citing Martell, *Systematic Review*, *supra* n.19); see also Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.22 (describing JAMA study that concluded opioids were not superior to non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen to treat longterm pain).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 37 of 214. PageID #: 37

includes approximately 100 million Americans – nearly one-third of the country's population.[52] The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made defendants billions of dollars. It has also led to the prevalence of opioid addiction and the overdose crisis in Chicago, in Illinois and nationwide.

2. The Fraudulent Sales Practices.

83. As set forth below, the Manufacturing Defendants employed a variety of strategies to normalize the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risk of addiction, overdose and death.

3. The Manufacturing Defendants Funded Front Organizations that Published and Disseminated False and Misleading Marketing Materials.

84. The Manufacturing Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Manufacturing Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

85. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. The Sacklers

[52] *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine, https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain (last visited Sept. 19, 2019).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 38 of 214. PageID #: 38

through Purdue, as well as Defendants Cephalon and Endo have provided substantial funding to the FSMB.

86. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled, "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to 700,000 practicing doctors.

87. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain. It contains lies such as, *"Opioid therapy to relieve pain and improve function is a legitimate medical practice for* acute and *chronic pain of* both cancer and *non-cancer origins*."[53]

88. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[54]

89. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction."[55] It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to

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[53] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).
[54] *Id.* at 9.
[55] *Id*. at 62.

assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[56] The guide, sponsored by the Manufacturing Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

90. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, *it's critical to remember that the problem of unrelieved pain remains as urgent as ever*.[57]

91. In another guide by Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[58] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

92. The heightened focus on the under-treatment of pain was a concept designed by Defendants to sell opioids. *The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain*.[59] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," a term which wholly lacked

[56] *Id*.
[57] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide* 10-11 (Waterford Life Sciences 2012).
[58] Scott M. Fishman, Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication 45 (Oxford Univ. Press 2012).
[59] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 40 of 214. PageID #: 40

scientific evidentiary basis but quickly became a common way for the Manufacturing Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox later became a Purdue vice president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University,[60] "If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[61]

93. As noted in §I ¶16 *infra*, in 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

94. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.[62] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated that "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" has been distributed in each of the 50 states and the District of Columbia.

95. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based

[60] Gounder, *Who Is Responsible*, *supra* n.47.
[61] Keefe, *Empire of Pain*, *supra* n.29.
[62] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley, https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 41 of 214. PageID #: 41

drugs from 1997 through the present. Included in the payments received are the following payments from the Sacklers through Purdue, and from other Defendants:

Company	***Fiscal Year***	***Amount***
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	***$822,400.06***
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Endo Payments	***$411,620.00***
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	***$180,000.00***
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	***$100,000.00***

96. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of “Responsible Opioid Prescribing” and disclosed that sales of “Responsible Opioid Prescribing” generated more than $2.75 million in revenues from sales in California alone.[63]

97. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturing Defendants, including the Sacklers through Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the “under-treatment of pain,” referenced pain as the “fifth vital sign” (the first

[63] *Id*. at 15.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 42 of 214. PageID #: 42

and only unmeasurable/subjective "vital sign") that must be monitored and treated and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

98. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies, claiming "*there is no evidence that addiction is a significant issue when persons are given opioids for pain control*." The book was sponsored by Purdue.

99. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[64]) collaborated to issue a 101-page monograph titled, "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous."[65]

100. The Manufacturing Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[66] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[67]

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[64] Funded by Johnson & Johnson, Purdue and Teva, among others.
[65] National Pharmaceutical Council, Inc., *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).
[66] *Id*. at 119.
[67] *Id*. at 42.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 43 of 214. PageID #: 43

101. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[68]

102. **The American Pain Foundation**: The American Pain Foundation ("APF"), described itself as the nation's largest organization for pain patients.[69] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from the Sackler Family (through Purdue), and defendants Endo, Janssen and Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of the APF's promotion of prescription opioids.

103. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[70]

104. For example, in 2001, the APF published "Treatment Options: A Guide for People Living with Pain."[71] The guide, which was produced due to support from companies

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[68] Gounder, *Who Is Responsible*, *supra* n.47. U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

[69] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.

[70] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/ (hereinafter, "Ornstein, *American Pain Foundation*").

[71] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Dec. 14, 2018).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 44 of 214. PageID #: 44

including Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "*[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings* as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[72]

- stated that "[o]pioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma";[73] and

- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[74]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[75]

105. In 2009, Endo sponsored the APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"). Among other false statements, Exit Wounds reported: "Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications*."[76] Endo, through the APF, thus distributed false information with the purpose of providing veterans false information they could use to self-advocate for opioids while omitting a discussion of the risks associated with opioid use.

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[72] *Id*. at 11.
[73] *Id*.
[74] *Id*. at 15.
[75] *Id.* at 76.
[76] Derek McGinnis, Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families, American Pain Foundation (2009), 107.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 45 of 214. PageID #: 45

106. In 2009, the APF played a central role in a first-of-its-kind, web-based series called, "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

> [**Teresa Shaffer (APF Action Network Leader)**:] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [**Dr. Al Anderson (AAPM Board of Directors)**:] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor *when they are suffering from pain for a long period of time*, especially *moderate* to severe pain. And *that's the patients that we really need to use the opioids* methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to have their pain controlled enough so that they can increase their quality of life.[77]

107. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[78] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and that they may actually reduce function.[79] As a recent article in the *New England*

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[77] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.
[78] Lembke (2016), supra n.18 at 59.
[79] Discussing the CDC's "March 2016 Guidelines for Prescribing Opioids for Chronic Pain," doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or qualify of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have

Journal of Medicine concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[80] More recent still, a study published in *JAMA* concluded that "[t]reatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[81]

108. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as a benefit of opioid therapy. In a brochure available on painknowledge.org titled, "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[82]

> showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guidelines*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), https://www.nejm.org/doi/full/10.1056/NEJMp1515917.

[80] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016).

[81] Krebs, *Effect of Opioid vs. Nonopioid Medications*, supra n.22.

[82] *Pain: Opioid Facts*, Pain Knowledge (2007) https://web.archive.org/web/20101007102042/

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 47 of 214. PageID #: 47

109. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "*common misconception*[]":

> *Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive*. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[83]

110. The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.[84]

111. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed the APF's close ties to drugmakers:

> *The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions*, an examination by ProPublica found.[85]

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http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Oct. 1, 2019).

[83] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5 (Oct. 2011), https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[84] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, *the other analgesics were significantly more effective than were opioids*." Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

[85] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-successof-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 48 of 214. PageID #: 48

112. **American Academy of Pain Medicine (AAPM) and American Pain Society (APS)**: The Manufacturing Defendants, including at least Endo, Janssen and the Sackler Family through Purdue, have contributed funding to the AAPM and the APS for decades.

113. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. At the time, the chairman of the committee that issued the statement, Dr. J. David Haddox, was a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well documented as set forth below.

114. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by Veterans Affairs adopting that campaign as part of its national pain management strategy.

115. The AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from Janssen, Cephalon, Endo or Purdue.

116. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[86] The 2009 Guidelines have been a particularly effective channel of

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[86] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 49 of 214. PageID #: 49

deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain*, have been cited hundreds of times in academic literature and remain available online. The Manufacturing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

117. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[87] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[88] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list included Johnson & Johnson, Endo, Mallinckrodt, Purdue, Cephalon and Allergan.

118. APA's board members have also directly received substantial funding from pharmaceutical companies.[89] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from Endo, Insys, Purdue and Cephalon. Nalamachu's clinic

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5900(08)00831-6/pdf (hereinafter, "Chou, *Clinical Guidelines*").

[87] *About AfPA*, The Alliance for Patient Access, http:// allianceforpatientaccess.org (last visited Dec. 14, 2018). References herein to APA include two affiliated groups: The Global Alliance for Patient Access and the Institute for Patient Access.

[88] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter, "Jaklevic, *Non-profit Alliance for Patient Access*").

[89] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 50 of 214. PageID #: 50

was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[90] Other past and present board members have included Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

119. Among its activities, the APA issued a white paper titled, "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[91] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, unfair to physicians, and of questionable efficacy.[92]

120. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . .

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[90] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), https://www.kansascity.com/news/business/health-care/article162569383.html.

[91] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), https://1yh21u3cjptv3xjder1dco9mx5s-wpengine.netdna-ssl.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[92] *Id*. at 4-5 (footnote omitted).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 51 of 214. PageID #: 51

[I]t is not even certain that the regulations are helping prevent abuses.[93]

121. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers.[94]

122. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[95]

123. ***Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Groups***: A February 12, 2018 report titled, "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" and issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member Claire McCaskill's Office, sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[96]

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[93] *Id*. at 5-6
[94] *Id*. at 6.
[95] *Id*. at 7.
[96] *February 2018 McCaskill Report*, *supra* n.16.

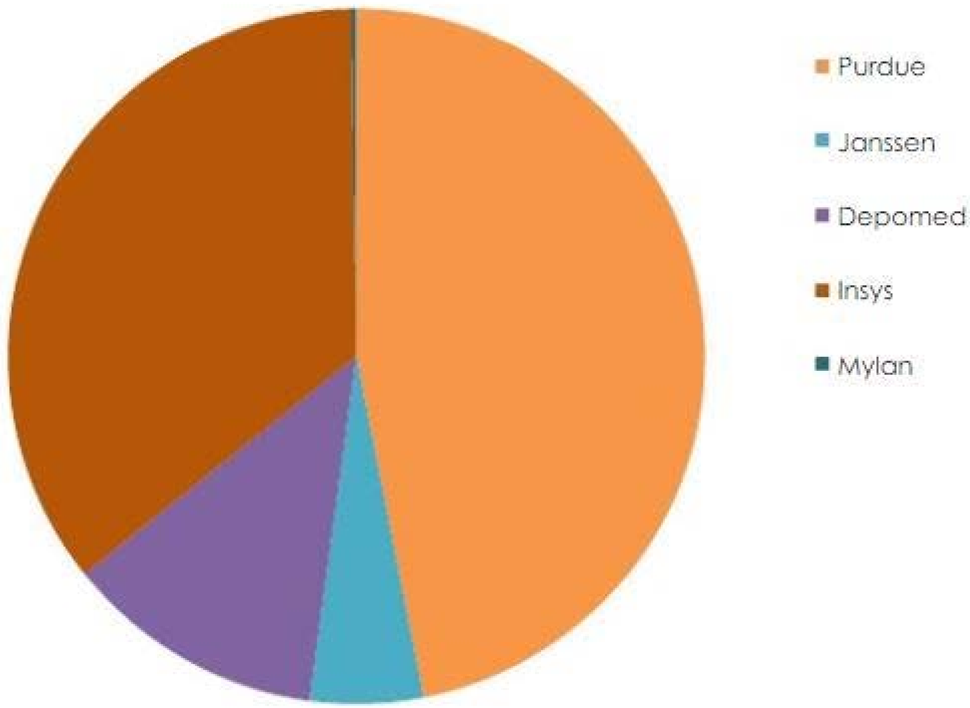
124. According to the report, the five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

125. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount:

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



126. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	**$4,153,554.33**
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				**$465,152.85**
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	**$1,071,116.95**
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	**$3,146,265.00**
Mylan				$15,000.00	$2,500.00	$2,750.00	**$20,250.00**
Total	**$1,151,250.71**	**$1,275,878.00**	**$1,086,251.95**	**$1,830,369.00**	**$878,824.99**	**$2,633,764.48**	**$8,856,339.13**

127. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies'

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 54 of 214. PageID #: 54

group executives, staff members, board members and advisory board members. When payments from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

128. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Endo, Purdue and Mallinckrodt, to ten members of the American Chronic Pain Association Advisory Board; $170,000 from Insys to National Pain Foundation ("NPF") chairman and founder D. Daniel Bennett; and more than $950,000 to members of the NPF board of directors from various opioid manufacturers, including more than $250,000 from Insys alone.

129. Worse still, the organizations provided limited disclosures of these sources of funding – when they provided any information at all. The American Society of Pain Educators,

the NPF, and the Academy of Integrative Pain Management provided no information concerning their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any information concerning donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specifics such as donation amounts.

130. Most importantly, many of the groups investigated "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[97] The report provided details regarding four ways the groups investigated set about these tasks.

131. First, the report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain."[98] The report provides examples, including the AAPM's and APS's 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low and the 2009 issuance of guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history.

132. In conclusion, the report found that, while health advocacy organizations are "among the most influential and trusted stakeholders in U.S. health policy," the reality is that their "positions closely correspond to the marketing aims of pharmaceutical and device

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[97] *Id*. at 12.
[98] *Id*.

companies," including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[99]

4. The Manufacturing Defendants Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging.

133. The Manufacturing Defendants have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Recently released federal data shows that the Manufacturing Defendants increased such payments to physicians who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[100] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs and other freebies. The total payments from the Manufacturing Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[101] Physicians who are high prescribers are more likely to be invited to participate in defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[s]peakers' bureau activities fall squarely within this definition of peer selling and hence product endorsement."[102]

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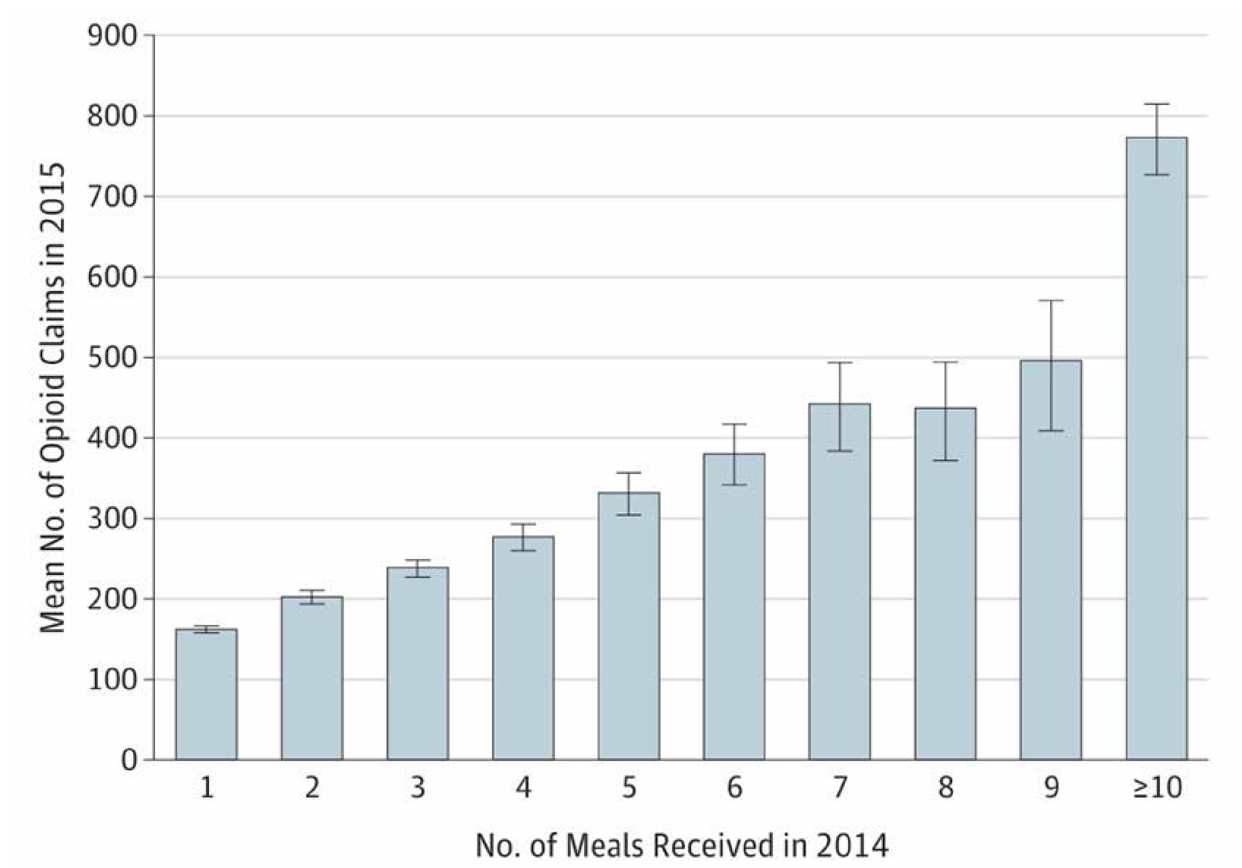
[99] *Id*. at 17.
[100] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.
[101] *Id*.
[102] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

134. According to a research letter published in *JAMA Internal Medicine* on May 14, 2018, doctors' mean number of opioids prescriptions increased with the number of free meals they received from an opioid company.[103] The study found that Insys accounted for 50% of the non-research payments.[104]



135. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. A 2013 publication by the Institute on Medicine as a Profession summarized that

[103] Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, JAMA Intern. Med. (May 14, 2018), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681059. The study looked at the Open Payments database, which was used to pull out non-research payments to doctors in 2014. It then compared that data to claims in the Medicare Part D Opioid Prescriber Summary File from doctors who wrote opioid prescriptions in 2015, leaving in "all physicians with complete, nonduplicate information who had at least 10 opioid claims during 2015."
[104] *Id.*

the bureaus "leverage the credibility of physicians in order to promote the use of pharmaceutical products" and "Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing."[105]

136. For example, Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled, "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[106]

137. Similarly, Fine's ties to the Manufacturing Defendants have been well documented.[107] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500

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[105] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf (citing research in *JAMA*, *The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*).

[106] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13), JAMA 1445 (2011), https://jamanetwork.com/journals/jama/article-abstract/1104464.

[107] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 59 of 214. PageID #: 59

pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.[108] He has also acknowledged having failed to disclose numerous conflicts of interest.

138. Fishman and Fine are only two of the many physicians whom the Manufacturing Defendants paid to promote false or biased information on the use of opioids for chronic pain.

5. Senate Investigations of the Manufacturing Defendants.

139. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

140. The Senate Finance Committee sent letters to Purdue, Endo and Johnson & Johnson, as well as five groups that support pain patients, physicians or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission. The letters addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible.[109]

141. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. They asked about any

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[108] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), https://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

[109] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society (footnote added).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 60 of 214. PageID #: 60

influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." In 2018, the Finance Committee demanded discovery detailing payments from the Manufacturing Defendants to nonprofit front groups, including those described above and the U.S. Pain Foundation,[110] American Academy of Pain Medicine, American Pain Society, and Center for Practical Bioethics, dating back to 1997.[111] The opioid report resulting from this investigation has not been released publicly.[112]

142. On March 29, 2017, it was widely reported[113] that yet another Senate investigation had been launched by Missouri Senator Claire McCaskill targeting the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

143. On September 6, 2017, Senator McCaskill's first report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," was published. The report found that Insys manipulated the prior authorization process by misleading pharmacy benefit managers ("PBMs") in order to increase sales of the Insys-manufactured opioid,

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[110] Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018), available at https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20the%20U.S.%20Pain%20Foundation.pdf.

[111] Thomas Sullivan, Senate Finance Committee Reacts to Reports of Opioid Abuse and Conflict of Interests: Letters to Manufacturers and Organizations (May 6, 2018), https://www.policymed.com/2012/05/senate-finance-committee-reacts-to-reports-of-opioid-abuse-and-conflict-of-interests-letters-to-manufactures-and-organizatio.html.

[112] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.70.

[113] Nadia Kounang, *Senator McCaskill opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), https://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 61 of 214. PageID #: 61

Subsys.[114] The PBM prior authorization process requires additional approval before dispensing and paying for certain powerful and expensive drugs, which, in the case of Subsys, included "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate."[115] The report found Insys actively and systematically misled PBMs about the presence of breakthrough cancer pain in potential Subsys patients to improperly circumvent the process, however.[116] On November 28, 2018, the former Vice President of Sales of Insys pled guilty in federal court to his role in a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe fentanyl-based pain medication and defraud healthcare insurers.

144. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated, "Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed."

145. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing.

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[114] *Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization*, U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's Office at 2 (Sept. 6, 2017), https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf.

[115] *Id.* (quoting Complaint, *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, (No. 2:17 CV 02286) (D. Ariz. July 12, 2017)).

[116] *Id.*

146. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

147. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis.

148. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

6. The Devastating Impact of the Manufacturing Defendants' Propaganda Campaign.

149. As stated, the impact of the Manufacturing Defendants' false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and died of overdoses.[117]

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[117] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), http://www.vox.com/2016/2/5/10919360/opioidepidemic-chart.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 63 of 214. PageID #: 63

150. Chicago and the State of Illinois, like the rest of the nation, are experiencing an unprecedented opioid addiction and overdose epidemic, costing millions in health insurance and public safety as well as lost productivity in the workforce.

151. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[118] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[119]

C. The Manufacturing Defendants' and Co-Conspirators' Specific Unlawful Practices that Targeted Illinois and Chicago-area Prescribers.

1. The Purdue Co-Conspirators

152. Purdue manufactures, markets, sells and distributes opioids in Chicago, in Illinois and nationwide, including the following:

OxyContin (oxycodone Hydrochloride extended release)	Opioid agonist[120] indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II

[118] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.
[119] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter, "Eban, *Painful Medicine*").
[120] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to elicit a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*, https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb?aq=difference+between+agonist+and+antagonist&qo=cdpArticles (last visited Sept. 17, 2019).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 64 of 214. PageID #: 64

MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.	Schedule II
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.160	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II

a) Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs.

153. At all relevant times, members of the Sackler Family – Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Beverly Sackler, Theresa Sackler, Ilene Sackler Lefcourt, David Sackler and the Raymond Sackler Trust – controlled Purdue and its related entities. This small group became extraordinarily wealthy because of their positions within Purdue and wielded immense amounts of power. Rather than use this power in a lawful and responsible manner, the Sacklers directed and oversaw Purdue's deceptive and unlawful sales and marketing practices.

154. The small and closely-held nature of Purdue and its associated entities makes the companies, in effect, the personal enterprises of the Sacklers. The Sacklers beneficially own and direct all the associate companies of Purdue in essentially the same manner as Purdue itself is controlled. All of Purdue's profits from opioids go to Sackler Family trusts and entities.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 65 of 214. PageID #: 65

155. The Sacklers caused Purdue and associate companies that they owned and controlled to distribute hundreds of millions of dollars in profit from the sale of opioids.

156. Because the Sacklers control Purdue's board, the officers of the company report directly to them, ensuring the Sacklers' control even if the company's officers were not themselves members of the families.

157. Each of the Sacklers named in this complaint has served on the board of directors of Purdue, and some of them have also served as officers of Purdue and/or one or more Purdue related associate companies.

158. Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[121] Prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[122] In its initial press release launching the drug, Purdue told doctors that one OxyContin would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and on Purdue's repeated assurances that opioids were both effective and non-addictive, OxyContin became America's bestselling painkiller.[123] Purdue had no evidentiary basis for those claims.[124]

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[121] Harriet Ryan et al., *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, "Ryan, *Description of Hell*").
[122] Keefe, *Empire of Pain, supra* n.29.
[123] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996), http://documents.latimes.com/oxycontin-press-release-1996/.
[124] Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 66 of 214. PageID #: 66

159. In truth, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early, as Purdue's own early studies showed, it is highly addictive.[125]

160. Furthermore, experts call the 12-hour dosing "'an addiction producing machine.'" Purdue had reportedly known for decades that it falsely promised 12-hour relief but nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

- Even before OxyContin went on the market, *clinical trials showed many patients weren't getting 12 hours of relief*. Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales reps and independent research.

- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price – up to hundreds of dollars per bottle – hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.

- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.

- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.

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shortly afterward. Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.29.

[125] The *Los Angeles Times* investigation, reported in three parts on May 5, July 10 and December 18, 2016, included the review of thousands of pages of confidential Purdue documents and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn testimony by executives, sales representatives and other employees. Ryan, *Description of Hell*, *supra* n.120. The *Los Angeles Times* reporters also examined FDA records, Patent Office files and medical journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 67 of 214. PageID #: 67

- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for the *Los Angeles Times*.[126]

161. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue promised the long-acting, extended-release formulation as safer and "less prone to such problems."[127]

162. Purdue's sales culture in Chicago, in Illinois and nationwide was one that required aggressive sales of its opioids and embraced the sell-at-any-cost notion: "sell or be gone." Aggressive quotas were put into place for opioids including OxyContin, at all dosage levels, as well as Hysingla products. The highest dosage for OxyContin was referred to by Purdue sales representatives as "hillbilly heroin." When sales representatives failed to meet their quotas, they were placed on performance employment plans and/or terminated. When they were successful, they were richly rewarded with extravagant bonuses and prizes.

163. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.

164. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical

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[126] Ryan, *Description of Hell, supra* n.120.

[127] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter, "Meier, *Guilty Plea*").

users of OxyContin."[128] "[B]y 2004 OxyContin had become a leading drug of abuse in the United States."[129]

165. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).[130]

b) Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians.

166. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk, Purdue also promoted the use of prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.[131]

167. Rather than targeting merely those physicians treating acute severe short-term pain, like postoperative pain physicians or oncologists treating end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin nationwide to doctors such as general practitioners, who often had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[132] According to a report in *The New Yorker*, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia" such that "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[133]

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[128] Van Zee, *Promotion and Marketing*, *supra* n.41.
[129] *Id.*
[130] Gounder, *Who Is Responsible*, *supra* n.47.
[131] Ornstein, *American Pain Foundation*, *supra* n.70.
[132] Meier, *Guilty Plea*, *supra* n.126.
[133] Keefe, *Empire of Pain*, *supra* n.29.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 69 of 214. PageID #: 69

168. Sales representatives plied these and other physicians with coupons that were redeemable for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent,'' and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic noncancer-related pain."[134]

169. Sales representatives marketed OxyContin as a product "to start with and to stay with," and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine.[135] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[136]

170. Further, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted." But "[i]n 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen percent."[137]

171. Even as late as 2015, if not later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had abuse-deterrent properties.

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[134] Van Zee, *Promotion and Marketing*, *supra* n.41.
[135] Keefe, *Empire of Pain*, *supra* n.29.
[136] *Id.*
[137] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 70 of 214. PageID #: 70

172. Purdue also tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from I.M.S. Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. (Notably, Arthur Sackler, who along with his brothers, Mortimer and Raymond, founded the Sackler family pharmaceutical businesses, co-founded I.M.S. Health.) Rather than reporting highly suspicious prescribing practices, Purdue used the data to track physicians who prescribed some opioids and might be persuaded to prescribe more. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.[138] It called the high-prescribing doctors "whales."[139]

173. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[140] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had reported only 8% of them to authorities. The *Los Angeles Times*

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[138] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), https://www.latimes.com/projects/la-me-oxycontin-part2/ (hereinafter, "Ryan, *More than 1 million*").

[139] Keefe, *Empire of Pain, supra* n.29.

[140] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015, 3:32 PM), http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrictmarketing-of-6464800.php.

reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[141]

c) Purdue Funded Publications and Presentations with False and Misleading Messaging.

174. As explained above, Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials. It extended far beyond, engaging third parties, including doctors and front groups, to spread the false message of prescription opioids' safety and efficacy.

175. Purdue caused the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors.

176. One of the advisors for Fishman's 2007 publication, "Responsible Opioid Prescribing: A Physician's Guide," and its 2012 update was Haddox, a longtime member of Purdue's speakers' bureau who later became a Purdue vice president.

177. Similarly,[142] multiple videos feature Fine delivering educational talks about the drugs. In one video from 2011 titled, "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[143] He states the "goal is to improve

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[141] Ryan, *More than 1 million*, *supra* n.137.
[142] Weber, *Two Leaders in Pain*, *supra* n.106.
[143] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 72 of 214. PageID #: 72

effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[144]

178. Purdue provided many "teaching" materials free of charge to the Joint Commission.

179. Purdue also deceptively marketed the use of opioids for chronic pain through the APF. Purdue paid the APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[145]

d) The Guilty Pleas.

180. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin for falsely marketing and promoting OxyContin as less addictive, less subject to abuse and diversion and less likely to cause tolerance and withdrawal symptoms than other pain medications in what the company acknowledged was an attempt to mislead doctors. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R.

[144] *Id.*
[145] American Pain Foundation, 2010 Annual Report at 16-19, https://assets.documentcloud.org/documents/277604/apf-2010-annual-report.pdf (last visited Dec. 15, 2018). Defendants Endo, Cephalon, and Janssen also made substantial payments to the APF in 2010: Endo more than $1 million, Cephalon between $50,000 and $99,999, and Janssen between $1,000 and $49,999. *Id*. at 19.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 73 of 214. PageID #: 73

Udell ("Udell"), Purdue's top lawyer, pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty and agreed to pay $7.5 million in fines.

181. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. *Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.*
>
> *But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures*. . . . OxyContin was the child of marketers and bottom line financial decision making.[146]

182. Brownlee characterized Purdue's criminal activity as follows:

> First, *Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse*. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, *Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction* than immediate release opioids.
>
> Third, *Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate release opioids resulting in less euphoria and less potential for abuse* than short-acting opioids.

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[146] Press Release, U.S. Department of Justice, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

> Fourth, *Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance* to the drug.
>
> And fifth, *Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids,* and could be used to "weed out" addicts and drug seekers.[147]

183. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin by introducing it into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

184. In 2019, the New York Times reported that a charging memo from the investigation, which was never released, confirmed that Purdue knew as early as 1996 that OxyContin was dangerously addictive and took steps to suppress that information.[148] This was despite the fact that Howard Udell, Purdue's General Counsel, testified in Congress and elsewhere that the company was unaware until early 2000 that OxyContin was being abused.[149]

185. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive, and continued to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007,

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[147] *Id*.

[148] John Pappas, Producer, The Weekly: Episode 10: The Memo, NYTIMES (Apr. 16, 2019), https://www.nytimes.com/2019/08/16/the-weekly/opioid-crisis-epidemic.html.

[149] Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, NYTIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 75 of 214. PageID #: 75

> it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.[150]

186. Purdue has earned more than $35 billion from OxyContin, the nation's bestselling painkiller.[151] The Sackler family received at least $8 billion in company profits during that time.[152]

187. Purdue also made payments to physicians in Chicago, in Illinois and nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

188. According to public records collected by ProPublica, in 2016 alone, Medicare Part D paid $17.4 million for claims arising from Illinois physicians' Oxycontin prescriptions.

e) The Sacklers Establish Rhodes as a "Landing Pad" from Purdue.

189. In or around November 2007, in the immediate aftermath of the guilty plea by Purdue and its executives regarding the company's false and misleading marketing of OxyContin, the Sacklers established Rhodes Pharmaceuticals. According to a former senior manager at Purdue, "Rhodes was set up as a 'landing pad' for the Sacklers in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin."[153]

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[150] Keefe, *Empire of Pain*, *supra* n.29.
[151] Laura Strickler, Purdue Pharma offers as much as $12 billion to settle opioid suits, NBC News (Aug. 27, 2019), https://www.nbcnews.com/news/us-news/purdue-pharma-offers-10-12-billion-settle-opioid-claims-n1046526.
[152] David Armstrong and Jeff Ernsthausen, Data Touted by OxyContin Maker to Fight Lawsuits Doesn't Tell the Whole Story, ProPublica, https://www.propublica.org/article/data-touted-by-oxycontin-maker-to-fight-lawsuits-doesnt-tell-the-whole-story.
[153] David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times (Sept. 9, 2018), https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

190. The Sacklers' involvement in Rhodes and its relationship to Purdue was not publicly known until the September 9, 2018 publication of an article in the *Financial Times*. According to the article, "Rhodes has not been publicly connected to the Sackler family before, and their ownership of the company may weaken one of their longstanding defenses: that they cannot be held responsible for the opioid crisis because Purdue accounts for a small fraction of the overall prescriptions."[154]

191. Despite being registered as a separate company from Purdue, staff from Rhodes and Purdue use the same employee handbook and "little distinction is made internally between the two companies."[155]

192. Rhodes manufactures, markets, sells and distributes the following opioids nationwide:

Hydromorphone hydrochloride	Generic opioid agonist.[156]	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic opioid agonist.	Schedule II
Oxycodone and acetaminophen	Generic opioid agonist.	Schedule II
Buprenorphine hydrochloride	Generic opioid agonist indicated for the treatment of opioid dependence.	Schedule III
Morphine sulfate	Generic opioid agonist.	Schedule II
Oxycodone hydrochloride	Generic opioid agonist.	Schedule II
Tapentadol hydrochloride	Generic opioid agonist.	Schedule II

[154] *Id.*
[155] *Id.*
[156] An agonist is a drug that activates certain receptors in the brain. Full agonist opioids activate the opioid receptors in the brain fully resulting in the full opioid effect. Examples of full agonists include heroin, oxycodone, methadone, hydrocodone, morphine, opium and others.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 77 of 214. PageID #: 77

193. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[157]

f) Purdue Failed to Monitor and Report Suspicious Sales as Required.

194. The Controlled Substances Act and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq*., impose on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

195. Purdue is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

196. Purdue failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue also failed to report to the Board sales of dangerous drugs subject to abuse. Purdue's failure to timely report these and other suspicious sales violated the CSA.

2. The Sackler Family Co-Conspirators

a) The Individual Sacklers Direct and Control Purdue.

197. Richard Sackler is one of the six inventors listed on the original patent for OxyContin. He began working for Purdue in the 1970s as an assistant to his father, Raymond Sackler, who served as the president of the company at that time. Richard rose through leadership in the subsequent decades, serving as President of Purdue from 1999 to 2003.

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[157] *Id.*

198. Richard Sackler resigned from his role in 2013 over apparent worry that executive officers of Purdue would be held personally liable for any opioid-related liabilities. He continued to serve as co-chair of Purdue's board with his uncle, Mortimer Sackler. This allowed the Sacklers to retain control of the company regardless of their involvement at the executive level.

199. During his executive tenure at Purdue, Richard Sackler actively participated in nearly every aspect of the company's opioid products, from invention to marketing to sale. With the assistance of his father, Raymond, and his uncle, Mortimer, Richard introduced OxyContin to the market with one of the largest pharmaceutical advertising campaigns in history. Within five years, OxyContin was earning Purdue $1 billion a year.

200. At all relevant times, Richard Sackler served as trustee of one or more trusts that own and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

201. Jonathan Sackler served as Senior Vice President of Purdue by 2000. Like Richard, his brother, Jonathan resigned from his position in or after 2003, due to concerns that the executive officers of Purdue would be personally liable for crimes and litigation stemming from Purdue's opioid products. Jonathan continued to serve on Purdue's board after his resignation.

202. At all relevant times, Jonathan Sackler served as trustee of one or more trusts that own and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

203. Mortimer Sackler is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

204. Kathe Sackler, Mortimer's daughter, began serving as Senior Vice President of Purdue by 2000. She resigned from her position in or about 2003 due to concerns that the executive officers of Purdue could be held personally liable for crimes and litigation stemming from Purdue's opioid products. She continued to serve on Purdue's board. She is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

205. Ilene Sackler Lefcourt, another of Mortimer's daughters, served as Vice President of Purdue during the initial development and launch of OxyContin. She, too, resigned from her position around 2003 due to concerns of personal liability for executive officers of Purdue for opioid-related crime and litigation, but continued to serve on the board.

206. Beverly Sackler, Raymond's wife, has served on the Board of Directors of Purdue and associated entities since the 1990s. She serves as the trustee of one or more trusts that own or control Purdue and Purdue associated companies, and to which 50% of the profits of the companies' sale of opioids have been conveyed. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by Purdue through the sale of opioids.

207. Theresa Sackler, Mortimer's wife, has served on the Board of Directors of Purdue and associated entities since the 1990s. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by Purdue through the sale of opioids.

208. David Sackler, Richard's son, has served on the Board of Directors of Purdue and associated entities since 2012. He is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue through the sale of opioids.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 80 of 214. PageID #: 80

209. Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler and the Raymond Sackler Trust (through its trustees) each knowingly aided, participated in and benefited from the unlawful conduct of Purdue.

b) The Sacklers Oversee and Direct Purdue's Unlawful Conduct.

210. Arthur Sackler, the brother of Raymond and Mortimer Sackler, is largely responsible for this change in public perception with regard to the purportedly safe uses of opioids. He was a psychiatrist and investor who effectively created the modern pharmaceutical advertising industry. He realized that direct advertising to doctors and prescribers would be the most effective means of turning a profit. He paid prominent doctors to endorse his products, offered physicians perks and benefits, published marketing material disguised as neutral medical journal articles and funded "education" seminars that extolled the virtues of his drug products. His deceptive and unethical marketing techniques led to Valium becoming the first hundred-million-dollar, then billion-dollar, prescription drug, and set the precedent for the current problems with pharmaceutical marketing.

211. The Sacklers have continued to direct Purdue's unlawful marketing techniques, using many of the same unethical techniques developed by Arthur Sackler in order to maximize their sales of opioid products.

212. OxyContin was launched with one of the largest pharmaceutical marketing campaigns in history, with roughly 1,000 sales representatives touting the drug's benefits. Representatives would recommend OxyContin as the solution not just for acute, short-term pain, but also for less-acute, longer lasting pain. Sales training included lessons in overcoming doctors' concerns about health and addiction by minimizing or downplaying OxyContin's true

qualities. Purdue paid thousands of physicians to present to medical conferences on the benefits of OxyContin.

213. The Sacklers were deeply involved in OxyContin's marketing campaign. Sacklers were on site at Purdue's headquarters daily, controlling the management of the family business. According to a former sales representative, Richard Sackler was "the dude that made it happen." In response to the concerns of benefit plans that OxyContin was ripe for addictive use, Richard sent an email to sales representatives, asserting that "'addiction' may be a convenient way for insurance companies to just say "NO" to coverage.[158]

214. In 1997, Richard and Kathe Sackler took part in a conspiracy to mislead doctors by claiming oxycodone was half as strong as morphine when the opposite was the case. Purdue engaged in this deception to alleviate the fears of medical professionals in prescribing the drug for non-acute pain.

215. Around 1999 to 2003, Purdue had a system where company emails would self-erase after pre-determined times. This policy created a system where potentially incriminating documents would be automatically erased even if received by third parties. Richard, Jonathan and Kathe Sackler were all aware and supportive of this system.

c) Sacklers Were Aware of the Abuse Potential of OxyContin Since at Least 1996.

216. Purdue and the Sacklers were aware that OxyContin and other prescription medication could lead to addiction since at least 1996. Indeed, the inventor of OxyContin, Robert Kaiko, wrote to Richard Sackler to oppose the idea of selling OxyContin as a "non-narcotic." He warned "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote "oxycodone containing products are still

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[158] Keefe, *Empire of Pain*, *supra* n.29.

among the most abused opioids in the U.S." and he predicated: "If OxyContin is uncontrolled, … it is highly likely that it will eventually be abused." Richard responded: "How substantially would it improve your sales?"[159]

217. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the misconception that OxyContin was weaker than morphine, which led them to prescribe it more often, even as a substitute for Tylenol. Richard Sackler ordered Purdue staff not to correct the misconception, because it could harm OxyContin's sales.[160]

218. In 1999, an internal memo prepared by Purdue employee Maureen Sara described the abuse and recreational use of OxyContin. The memo was sent directly to Purdue's board members, including Richard, Jonathan and Kathe Sackler.

219. In spite of the 1999 memo, Purdue President Michael Friedman testified before the U.S. House of Representatives in 2001 that Purdue had not become aware of OxyContin's potential for abuse until 2000. None of the Sacklers or anyone else at Purdue attempted to correct this false narrative.

220. The Sacklers were thus aware of potential liability for Purdue since at least 1999 due to OxyContin's addictive nature. Instead of attempting to fix or solve the issue they had created, the Sacklers began to transfer profits from Purdue and associated companies to their own private trusts and accounts in order to shield their funds from creditors. In 2015, for example, the Sacklers removed $700 million from their privately held companies, two-thirds of which came from Purdue. These transfers of ill-gotten gains were and are fraudulent, unjustly

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[159] Complaint, *Commonwealth of Mass v. Purdue Pharma L.P., et al.*, C.A. No. 1884-cv-01808 (BLS2), ¶ 174 (Mass Supr. Ct. Jan. 31, 2019) (hereinafter "Mass Complaint"), https://assets.documentcloud.org/documents/5716943/Massachusetts-AGO-Amended-Complaint-2019-01-31.pdf.
[160] *Id*. at ¶ 176.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 83 of 214. PageID #: 83

enriched the Sackler and were done for the purpose of protecting the money from any civil or criminal judgment against Purdue for its participation in the opioid crisis. These transfers also left Purdue and its associated entities undercapitalized and potentially unable to pay a judgment against it in this litigation.

221. In 2001, Richard Sackler received word from a Purdue sales representative that he had attended a community meeting at a local high school organized by mothers whose children overdosed on OxyContin and died. "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."[161]

222. In 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

223. In March, 2001, the New York Times and Time Magazine published articles about widespread deaths related to OxyContin.[162]

224. The next month, Richard Sackler wrote in an email his strategy for discounting the overwhelming evidence that OxyContin caused widespread abuse and death: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."[163]

225. That spring, Purdue executives met with the DEA. A senior DEA official, who sat across from Rickard Sackler, leaned over the table and told him: "People are dying. Do you understand that?"[164]

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[161] *Id*. at ¶ 181.
[162] *See* Barry Meier, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost*, NYTimes (Mar. 5, 2001), https://www.nytimes.com/2001/03/05/business/sales-of-painkiller-grew-rapidly-but-success-brought-a-high-cost.html.
[163] *Id*. at ¶ 183.
[164] Barry Meier, Pain Killer: A "Wonder" Drug's Trail of Addiction and Death, Rodale (2003).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 84 of 214. PageID #: 84

226. In March 2013, staff reported to the Sacklers on the devastation caused by prescription opioids. Staff told the Sacklers that drug overdose deaths had more than tripled since 1990—the period during which Purdue had made OxyContin the best-selling painkiller. They told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg," and that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

227. Just two months later, at a May 2013 board meeting, staff reported to the Sacklers that they were successfully pushing opioid savings cards through direct mail and email to get patients to "remain on therapy longer."

d) The Sacklers' Full Understanding Of Opioid Abuse And Addiction Risk is Underscored By Their Pursuit of Business Opportunities In Medications That Treat Addiction Their Own Opioids Caused.

228. In 2007, Richard Sackler applied for a patent to treat opioid addiction. He finally received it in January 2018 and assigned it to Rhodes, the "landing pad" company set up and controlled by the Sacklers, instead of Purdue. Richard's patent application says opioids are addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.

229. In September 2014, Kathe Sackler participated in a call about Project Tango—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, defendant Kathe Sackler and staff memorialized what Purdue publicly denied for decades: "Pain treatment and addiction are naturally linked." The team reviewed findings that the "market" of people addicted to opioids had doubled from 2009 to 2014.

230. Kathe Sackler ordered staff's "immediate attention, verification, and assessment" of reports that children requiring hospitalization after swallowing a film that melts in your

mouth, and staff assured Kathe that children were overdosing on pills like OxyContin, not films, “which was positive for Tango.”

231. In February 2015, staff presented Kathe Sackler’s work on Project Tango to Purdue’s board. The plan was for a joint venture controlled by the Sacklers to sell the addiction medication suboxone and would result in the Sackler’s acquisition of a substantial share of the addiction medicine market.

232. During the presentation, the Tango team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue's OxyContin or heroin, and then become consumers of the new company's suboxone. The team noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

233. In June 2016, the Sacklers met to discuss a revised version of Project Tango and considered a scheme to sell the overdose antidote NARCAN. At this meeting, the Sacklers and the Purdue board calculated that the need for NARCAN to reverse overdoses could provide a growing source of revenue, tripling from 2016 to 2018.

234. The Sacklers identified patients on Purdue's prescription opioids as the target market for NARCAN. Their plan called for studying "long-term script users" to "better understand target end-patients" for NARCAN. The Sacklers planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use NARCAN to save lives.

235. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of Project Tango to discuss acquiring a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 86 of 214. PageID #: 86

Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."

236. In September 2019, two years after these MDL proceedings began, the same week that Purdue and the Sacklers reached a tentative settlement with 23 states and thousands of local governments, and less than one week before Purdue filed for bankruptcy, the New York attorney general's office disclosed that it had uncovered about $1 billion in secret, previously undisclosed wire transfers between the Sackler family and international financial institutions, suggesting the Sacklers were engaged in stashing their wealth in overseas bank accounts to attempt to conceal them from consideration in the pending litigation and preliminary settlement .[165]

e) The Sacklers Continued to Oversee Purdue's Wrongdoing Even After Repeated Warnings and Fines.

237. The liability of the Sacklers extends beyond their leadership of Purdue. They were aware of, and obligated to address, Purdue's conduct due to previous investigations into the company's deceptive practices.

238. Purdue Pharma Inc. and Purdue Pharma L.P. were under investigation by 26 states and the DOJ from 2001 to 2017. In 2003, on the advice of legal counsel, every Sackler who held an executive role at Purdue resigned to avoid personal liability for the conduct in which they had engaged and continued to engage prior to and after their resignations. But the Sacklers retained ownership and control of the company.

239. In 2007, the directors of Purdue Pharma Inc. declared that it would pay roughly $700 million and plead guilty to a felony for misleading doctors and patients about opioid medications. (The company that paid the money, the Purdue Frederick Company, was the

[165] Deanna Paul, *N.Y. attorney general exposes $1 billion in wire transfers by Sackler family*, Washington Post (Sept. 14, 2019) https://www.washingtonpost.com/business/2019/09/14/ny-attorney-general-exposes-billion-wire-transfers-by-sackler-family/.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 87 of 214. PageID #: 87

original pharmaceutical company purchased by Arthur Sackler and his brothers, and while it was technically a separate corporate entity, it was controlled by the same people and shared the same headquarters as Purdue Pharma L.P.). The company acknowledged that its supervisors and employees had fraudulently promoted OxyContin as safer and less addictive than other pain medications.

240. Michael Friedman, the Chief Executive Officer ("CEO") of Purdue, pled guilty to criminal charges of fraudulent marketing. Udell, Purdue's chief lawyer, and Goldenheim, Purdue's chief medical officer, pled guilty to the same crime.

241. The 2007 convictions warned the directors against any further deception.

242. The directors also agreed to a Consent Judgment that ordered Purdue not to make any false or misleading oral or written claims about OxyContin, including concerning the risk of addiction. The Consent Judgment also required Purdue to establish a program that would identify high-prescribing doctors, stop promoting OxyContin to them and report them. This program was to last from 2007 to 2017.

243. The directors also entered a Corporate Integrity Agreement with the U.S. government, wherein Purdue would appoint a compliance officer to a senior management position at Purdue. The officer would make periodic reports on compliance matters to the board to ensure no deception took place again. Under the agreement, the directors and CEO were "Covered Persons" who had to comply with rules prohibiting deception regarding Purdue's products. This status lasted from 2007 to 2012 and required that leadership report all rule violations and undergo hours of compliance training. The directors and CEO were warned of consequences in case of a violation and certified that they understood their new status.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 88 of 214. PageID #: 88

244. Purdue's directors were clearly aware of their obligations under the above agreements. In 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services ("HHS") that it had not immediately trained a new director on the terms of the Corporate Integrity Agreement. Purdue assured the government that the director had undergone the training the day after Corporate Compliance had learned of the issue.

245. The years after the 2007 guilty plea and Corporate Integrity Agreement were filled with alarming reports and stories about the opioid crisis. However, in spite of these widespread warnings, Purdue's directors, including the Sacklers, did nothing to stop Purdue's misconduct.

246. From 2007 through 2018, the Sacklers controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives, who visited doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed the representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to authorities. They sometimes demanded more detail than others in the entire company, so staff had to create special reports just for them. Richard Sacker even went into the field to promote opioids to doctors and supervise representatives personally.

247. The Sacklers' micromanagement was so intrusive that staff begged for relief. In fact, Vice President of Sales and Marketing wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is much appreciated."[166]

[166] Complaint, ¶ 54, *State of New Hampshire v. Richard Sackler, et al.*, 217-2019-CV-00617 (N.H. Super. Ct. Sept. 16, 2019) (hereinafter "New Hampshire Complaint").

248. Upon information and belief, the Sacklers voted to direct Purdue to pay their family billions of dollars, including profits from opioids. These payments show the absolute control that the Sacklers exercised over Purdue.

249. On April 18, 2008, Richard Sackler sent Kathe, Jonathan, and Mortimer Sackler a memo about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard recommended John Steward for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.[167]

250. That month, the Sacklers voted to have Purdue pay their family $50 million. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's opioid profits to their family—in total more than four billion dollars.[168]

251. In 2008, opioid overdoses killed more Americans in that year than any year prior.

252. In 2009, the *American Journal of Public Health* published "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy."[169] The article detailed the misleading and deceptive nature of Purdue's opioid marketing, including the misuse of sales representatives, the targeting of high-prescribing practitioners and deception about the potential

[167] *Id.* at ¶ 58.
[168] *Id.*
[169] Van Zee, *Promotion and Marketing*, *supra* n.41.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 90 of 214. PageID #: 90

rates of abuse. The CDC reported that deaths stemming from opioid use had tripled in the preceding year.

253. In 2010, *Time* magazine published "The New Drug Crisis: Addiction by Prescription."[170] The article focused extensively on Purdue's line of opioid products. Overdoses were the number one cause of accidental death in 15 states that year, and Purdue's directors were informed that Purdue would not be able to get product liability insurance to cover OxyContin.

254. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for educating healthcare providers about prescription drug abuse to prevent over prescription. The CDC announced that prescription opioid overdoses had reached never before seen levels and specifically called out Purdue's line of opioid products. *Fortune* magazine published an article that same year where Purdue executives were interviewed about the ongoing crisis and the involvement of the company and the Sacklers. The interviewees included Purdue Vice President Alan Must, who admitted that Purdue was "well aware" of concerns about its conduct: "We are well aware of detractors. For those individuals who think we're evil . . . I don't think there's anything we can do that is going to change their opinion."[171]

255. In 2012, the U.S. Senate announced an investigation into Purdue's unlawful deception of doctors and patients about the nature of its opioid products. The Senate specifically warned the directors and CEO that they were under scrutiny, demanding that Purdue present a set

[170] Jeffrey Kluger, *The New Drug Crisis: Addiction by Prescription*, TIME (Sept. 17, 2010), http://content.time.com/time/magazine/article/0,9171,2015763,00.html.
[171] Eban, *Painful Medicine, supra* n.118.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 91 of 214. PageID #: 91

of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."[172]

256. In 2013, the *Los Angeles Times* reported that Purdue had created a list of 1,800 doctors suspected of recklessly prescribing its opioids over the past decade but had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said with regard to Purdue's unwillingness to disclose the list: "I don't really want to open up an opportunity for folks [to] come in here and start looking and second guessing."[173]

257. Abrams and Purdue's directors had good reason to be concerned: the state of Kentucky had brought a lawsuit against Purdue for deceiving doctors and patients about the nature of its opioid products. When Purdue's lawyers surveyed the local residents for potential jury service, one-third of respondents said they knew someone who had been hurt or had overdosed taking Purdue opioids, and 29% knew someone who had died. Purdue itself filed these findings in court.

258. In 2014, Edward Mahony, the Executive Vice President, Chief Financial Officer and Treasurer of Purdue, announced that the Kentucky lawsuit was noteworthy enough to "jeopardize Purdue's long-term viability."[174] The Governor of Massachusetts declared the opioid crisis a public health emergency in the same year.

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[172] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to John H. Stewart, President and CEO of Purdue Pharma, https://www.finance.senate.gov/imo/media/doc/Purdue_May_8.pdf.

[173] Scott Glover & Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, Los Angeles Times (Aug. 11, 2013), https://www.latimes.com/local/la-me-rx-purdue-20130811-story.html.

[174] Tracy Staton, *Addiction-riddled Kentucky out for blood in $1B suit against OxyContinmaker*

259. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sackers, controlled the operation of Purdue's sales representatives. Director Richard Sackler testified that Purdue primarily promoted its opioids through its sales representatives, and that regular visits from representatives were the key to get doctors to continue to prescribe the drugs. The board knew which drugs the sales representatives were to promote, the number of visits representatives made to doctors, how much each visit cost the company and the quarterly plans for sales visits. The board approved specific hiring plans for their sales representatives, hiring directors and regional managers and creating sales territories for representatives to target doctors.

260. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sacklers, oversaw the specific tactics used by sales representatives to sell opioids; for example, a board report encouraged the use of iPads during sales visits, which increased the average length of meetings to 16.7 minutes.

261. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sacklers, oversaw the promotional claims representatives used during sales visits. The directors and CEO reviewed reports that Purdue sales representatives were deceptively promoting opioids as an appropriate treatment for minor pain, among hundreds of other examples of unlawful marketing techniques in need of correction.

262. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sacklers, oversaw Purdue's research, which in some cases contradicted the company's marketing. Company leadership received detailed and specific reports concerning Purdue opioids being used for "opioid naïve" patients and patients with osteoarthritis.

Purdue, FiercePharma.com (Oct. 20, 2014), https://www.fiercepharma.com/pharma/addiction-riddled-kentucky-out-for-blood-1b-suit-against-oxycontin-maker-purdue.

263. Plaintiff is informed and believes, and thereupon alleges, that company leadership, including the Sacklers, was directly informed of "Reports of Concern" filed by sales representatives regarding high-prescribing doctors, as well as "field inquiries" in response to the reports.

264. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sacklers, monitored sales representatives' emails. Purdue had a policy of prohibiting sales representatives from communicating with doctors via email; when Purdue found that some representatives had in fact e-mailed doctors, the company "investigated" the matter and told the board that the representatives had been disciplined and the matter would be discussed at the next board meeting.

265. Plaintiff is informed and believes, and thereupon alleges, that the directors, including the Sacklers, oversaw Purdue's strategy to pay high-prescribing doctors to promote its opioids. The board was aware of the amount paid to specific high prescribers and the return on investment it received from these payments. The board knew that Purdue allowed a gift spending limit of $750 per doctor per year and was told specifically that paying doctors was a high-risk activity that could result in improper off-label use or other promotional activity for opioids.

266. Plaintiff is informed and believes, and thereupon alleges, that the directors and CEO, including the Sacklers, also managed Purdue's focus on encouraging patients to use higher and higher doses of opioids, leading to health issues, addiction and greater profits for the company. Upon learning that sales of 40mg and 80mg strengths of OxyContin had fallen below sales targets, the board received multiple reports that public health authority initiatives to have doctors consult with pain specialists before prescribing high opioid doses were a "threat." The

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 94 of 214. PageID #: 94

board oversaw measures to counteract against these initiatives and received reports in 2013 that attempts to encourage increased total daily doses had had a positive impact on the company's bottom line.

267. Plaintiff is informed and believes, and thereupon alleges, that the directors, including the Sacklers, additionally oversaw Purdue's plan to keep patients hooked on opioids for longer periods of time through higher doses. The board received thorough reports of how many patients remained on Purdue opioids for extended lengths of time, as well as internal documents that indicated patients on higher doses used the product for longer amounts of time, creating greater chances of addiction and abuse. The board was presented with a plan to create workshops and give specific direction to representatives about this link, and that increasing opioid use was a focus point of the company. The board was told in writing that encouraging higher doses "is a focal point of our promotion" and that sales representatives should push doctors to increase patient doses as soon as three days after initial treatment. The board knew or should have known that this sales tactic was both deceptive and placing patients at high risk of addiction and overdose.

268. Plaintiff is informed and believes, and thereupon alleges, that the directors, including the Sacklers, also oversaw Purdue's targeting of prescribers without special knowledge of opioids, as they were the most likely to respond to Purdue's sales techniques. Purdue proceeded with this strategy despite the DEA expressing concern that Purdue was marketing its opioids to doctors who were not appropriately trained in pain management. The directors and CEO knew or should have known both that this strategy was deceptive and that targeting doctors who lacked special training in pain management and elderly patients increased the risk of addiction and overdose.

269. Plaintiff is informed and believes, and thereupon alleges, that Purdue's leadership, including the Sacklers, was also aware of a plan to steer patients away from safer pain-management medicines, which involved efforts to emphasize the danger of acetaminophen-based pain medication to the liver. These efforts included deceptive websites that the New York Attorney General specifically held to be misleading in specific sections.

270. Plaintiff is informed and believes, and thereupon alleges, that Purdue's leadership, including the Sacklers, also oversaw the response to thousands of harm reports from patients, in one case receiving over 5,000 complaints in a single quarter.

271. Plaintiff is informed and believes, and thereupon alleges, that Purdue possesses documents that show each of the reports mentioned above was sent to every individual defendant on the board, including every Sackler with a board position.

3. The Johnson & Johnson Defendants.

272. Following a bench trial, on August 26, 2019, Judge Thad Balkman of the District Court of Cleveland County, Oklahoma entered judgement against Johnson & Johnson in *State of Oklahoma v. Purdue Pharma, L.P., et al.*. for $572,000,000 (representing damages for a single year) to abate the public nuisance caused by its actions related to manufacturing and marketing opioids in the state of Oklahoma.[175] Judge Balkman found that "Defendants engaged in false and misleading marketing of both their drugs and opioids generally, and the law makes clear that such conduct is more than enough to serve as the act or omission necessary to establish the first element of Oklahoma's public nuisance law."

273. Johnson & Johnson is the only company that owns more than 10 percent of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products.

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[175] *See* Judgement After Non-Jury Trial, *State of Oklahoma v. Purdue Pharma*, *et al*., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019) (hereinafter "Johnson & Johnson Judgement").

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 96 of 214. PageID #: 96

Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to Johnson & Johnson's benefit. Together, Johnson & Johnson and Janssen (the "Johnson & Johnson Defendants") 1) funded the production and dissemination of and disseminated false, misleading, and deceptive information about the efficacy and addictive properties of prescription opioids; 2) failed to monitor and report suspicious sales as required by federal law.

274. As part of its "pain management franchise" from the 1990s through at least 2016, Johnson & Johnson wholly owned Tasmania Alkaloids Limited ("Tasmanian Alkaloids"), which was based in Tasmania and cultivated and processed opium poppy plants to manufacture narcotic raw materials to be imported into the U.S. to be processed and made into active pharmaceutical ingredients (APIs) necessary to manufacture opioid drugs. It also wholly owned Noramco, Inc. which is based in Athens, Georgia and imported the raw narcotic materials produced by Tasmania Alkaloids, processed the materials into APIs, then sold the APIs to other opioid manufacturers in the U.S.[176]

a) Janssen

275. Janssen manufactures, markets, sells and distributes the following opioids in Chicago, in Illinois and nationwide:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

[176] Johnson & Johnson Judgement ¶ 6.

276. Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also marketed Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen marketed Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

277. In 1997, after seeing the success that Purdue had in marketing OxyContin for chronic non-cancer pain, the J&J Defendants re-launched their fentanyl-based Duragesic patch for the chronic, non-cancer market as well.

b) The FDA Warned Janssen Regarding Its False Messaging.

278. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §301, *et seq.* In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 98 of 214. PageID #: 98

279. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse.[177]

280. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved.[178]

281. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product."[179]

282. On September 2, 2004, HHS sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

283. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the

[177] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutical at 2 (Mar. 30, 2000), available at *County of Wayne and County of Oakland v. Purdue Pharma, et al*., No. 2:17-cv-13334-JCO-EAS, Dkt. 2-10 (E.D. Mich. Oct. 12, 2017).
[178] *Id*. at 2-3.
[179] *Id*. at 3 (emphasis in original).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 99 of 214. PageID #: 99

claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN.[180]

284. The September 2, 2004 letter also detailed a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

- "Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."
- "All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."
- "Significantly reduced nighttime awakenings."
- "Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."
- "Significant improvement in physical functioning summary score."
- "Significant improvement in social functioning."[181]

285. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 [lives] . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter stated:

[180] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004), http://www.johnsonandtoxin.com/ 040920_duragesic_letter.pdf.
[181] *Id*. at 2-3.

"Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[182]

286. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

287. Regardless, even after receiving these letters, Janssen instructed sales representatives in Chicago, in Illinois and nationwide to market Duragesic as having better efficacy, better tolerability and better patient compliance because it was a patch instead of a pill. These sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing, then chewing on it.

c) The Johnson & Johnson Defendants Funded False Publications and Presentations.

288. Janssen disseminated false information about opioids on the website Prescribe Responsibly. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[183] The website includes numerous false or misleading representations

[182] *Id.* at 3.
[183] *Legal Notice*, Prescribe Responsibly, https://web.archive.org/web/20171003192940/http://www.prescriberesponsibly.com/legal-notice

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 101 of 214. PageID #: 101

concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . analgesic therapy."[184]

289. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects: Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over NSAIDs.

> Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[185]

290. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[186] Thus, "pseudoaddiction" is defined as a condition requiring the prescription of more or stronger opioids.

(last visited Sept. 19, 2019).

[184] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, https://web.archive.org/web/20180714193514/http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Sept. 19, 2019).

[185] *Id.*

[186] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, https://web.archive.org/web/20180720092635/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited Sept. 19, 2019).

291. Another unbranded marketing initiative that Johnson & Johnson Defendants employed was the dissemination of a brochure, titled "Finding Relief," which was sponsored AAPM.[187] The Finding Relief brochure, which was widely disseminated, did not differentiate between different kinds of opioids and discussed them as a class of drugs without reference to any of the differences between them. The Finding Relief brochure actively promoted the concept that pain was undertreated. The brochure downplayed any risks associated with opioids.[188]

292. Janssen also made thousands of payments to physicians nationwide, including to Chicago-area physicians, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

293. The Oklahoma trial court found that Johnson & Johnson Defendants used a sales force to promote, market and sell various types of opioids, including branded opioid drugs that Johnson & Johnson and its subsidiary Janssen themselves manufactured: Duragesic, Ultram, and Nucynta.[189]

294. The Johnson & Johnson Defendants training of its sales representatives included teaching sales representatives to avoid the so-called "addiction ditch"—i.e. to avoid the negatives (addiction) and emphasize the positives (supposed efficacy) in sales calls—and to use a study from Dr. Portenoy "to create dialogue about Opiophobia as a barrier."[190]

295. As part of this training, the Johnson & Johnson trained their sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. As

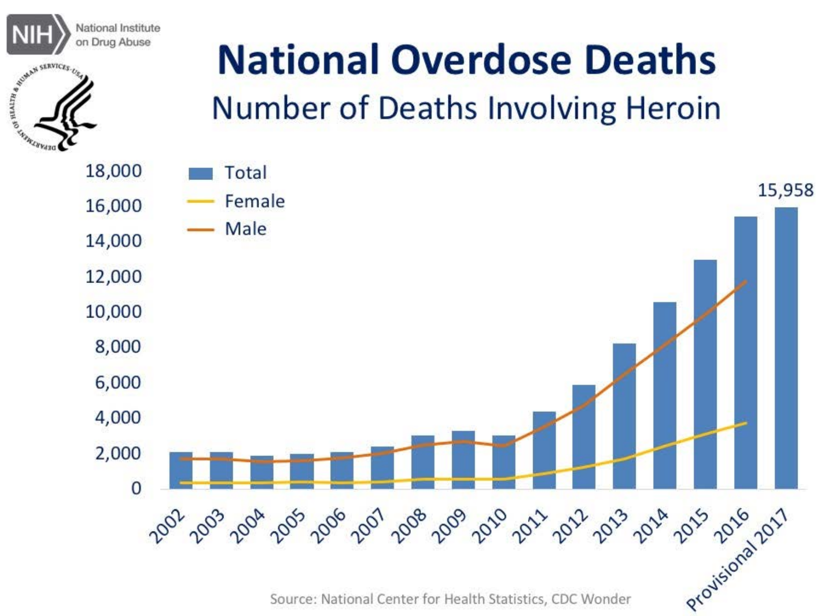
[187] Finding Relief: Pain Management for Older Adults (2009), available at https://docplayer.net/28610911-Finding-relief-pain-management-for-older-adults.html (last visited Sept. 27, 2019).
[188] Johnson & Johnson Judgement ¶ 24.
[189] *Id.* at ¶¶ 26- 29.
[190] *Id*. at ¶ 27.

part of this same training, Johnson & Johnson and Janssen trained sales representatives to "establish that moderate to severe acute pain continues to be undertreated."[191]

296. The Oklahoma trial court found that Johnson & Johnson and Janssen did not provide its sales force with any training on opioid addiction.

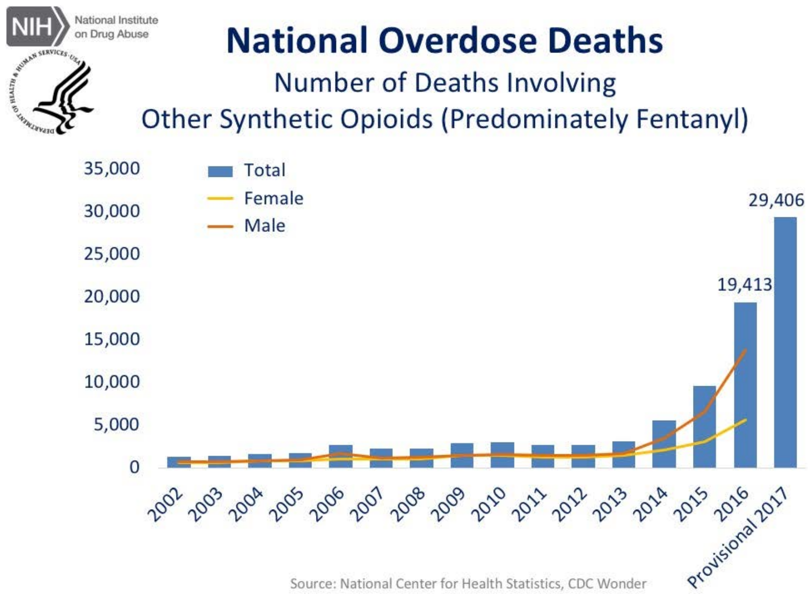
297. According to data collected by ProPublica, in 2016, Illinois doctors prescribed $785,000 worth of Duragesic, $1.32 million worth of Nucynta, and $1.56 million of Nucynta ER to patients insured by Medicare part D. On information and belief, a large percentage of these prescriptions were for patients in Chicago.

298. As people became more and more hooked on prescription painkillers, many moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and is increasingly mixed with or sold as heroin and, as set forth above, was also being deceptively marketed by Janssen. This transition to heroin and fentanyl caused a dramatic spike in heroin overdose deaths after 2011 and in fentanyl overdose deaths in 2014:



191 *Id*. at ¶ 28.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 104 of 214. PageID #: 104



d) The Johnson & Johnson Defendants Failed to Monitor and Report Suspicious Sales as Required by Federal Law.

299. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

300. The Johnson & Johnson Defendnats are "registrants" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

301. The Johnson & Johnson Defendants failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. They also failed to report to the Board sales of dangerous

drugs subject to abuse. Their failure to timely report these and other suspicious sales violated the CSA.

e) In addition to marketing its own opioids, Johnson & Johnson owned two companies that grew, imported, and processed the raw materials to make opioids and sold them to many of the other Manufacturing Defendants, including Purdue.

302. Until 2016, when Johnson & Johnson sold its Noramco/Tasmanian Alkaloids business, Tasmanian Alkaloids and Noramco were "sister companies," as "both of them were" members of Defendants' "family of companies." Noramco employees did not believe Noramco maintained its own bank accounts, separate from Johnson & Johnson's treasury. Johnson & Johnson, Noramco and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Johnson & Johnson's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within the Johnson & Johnson Family of Companies at times. During this time, Noramco and Tasmanian Alkaloids were key parts of Johnson & Johnson's "pain management franchise" or "pain franchise."[192]

303. Johnson & Johnson, through these subsidiaries, supplied the following opioid active pharmaceutical ingredients ("API") to other drug manufacturers in the U.S., including Purdue and Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.[193]

304. In the 1980s, Johnson & Johnson acquired and formed Tasmanian Alkaloids and Noramco, in order to ensure a "reliable source of [narcotic] raw materials" and "security of supply" for its Tylenol with Codeine range of pain medications.[194]

[192] Johnson & Johnson Judgement ¶ 7.
[193] *Id.* at ¶ 8.
[194] *Id.* at ¶ 9.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 106 of 214. PageID #: 106

305. Noramco, located in the U.S., imports the narcotic raw materials produced by Tasmanian Alkaloids, like morphine or thebaine,[195] into the U.S., processes them into APIs, then sells them to drug manufacturers in the U.S. Noramco was "an important part of J&J's business" from the mid-1990s until at least after 2010. Johnson & Johnson's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug manufacturers, including Johnson & Johnson itself, with "Security of Supply-Direct Access to Narcotic Raw Material - From Our Fields to Your Formulations." Through its subsidiary, Noramco, Johnson & Johnson supplied oxycodone API to other drug manufacturers.[196]

306. In 1994, Johnson & Johnson, in concert with subsidiary, Tasmanian Alkaloids, anticipated demand for oxycodone. Specifically, Johnson & Johnson scientists at Tasmanian Alkaloids began a project "in 1994 in order to develop a high thebaine poppy variety to meet the anticipated demand." The result of Defendants' research project was the creation of a "high thebaine" poppy called the "Norman Poppy," which Johnson & Johnson internally described as "a transformational technology that enabled the growth of oxycodone."[197]

307. Through Noramco, Johnson & Johnson met the anticipated opioid demand by selling API, including oxycodone, to Purdue.[198]

308. Through Noramco, Defendants supplied API to other opioid manufacturers, including Teva. Noramco sold the majority of its controlled substance via long-term agreements and had such agreements with all 7 of the top U.S. generic companies. Through Noramco,

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[195] Thebaine is an opiate alkaloid, chemically similar to morphine and codeine, used as an intermediate in the biosynthesis of other opioids.
[196] *Id.* at ¶ 10.
[197] *Id.* at ¶ 11.
[198] *Id.* at ¶ 12.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 107 of 214. PageID #: 107

Defendants supplied other U.S. opioid manufacturers with opioid APIs, including: oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone and naloxone.[199]

309. Noramco grew to become the number one narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States.[200]

4. Endo.

310. Endo manufactures, markets, sells and distributes the following opioids in Chicago, in Illinois and nationwide:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone was available in an oral, extended-release formulation; first approved in 2006.	Schedule II
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
Oxycodone	Generic product.	Schedule II
Oxymorphone	Generic product.	Schedule II
Hydromorphone	Generic product.	Schedule II
Hydrocodone	Generic product.	Schedule II

311. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated “for the relief of moderate to severe pain” and “for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular

[199] *Id.* at ¶ 14.
[200] *Id.* at ¶ 15.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 108 of 214. PageID #: 108

dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[201]

312. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus, it was marketed as being safer, with less abuse potential than OxyContin because it is supposed to be crush-resistant.

313. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

a) Endo Falsely Marketed Opana ER as Crush Resistant.

314. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the new version "is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where

[201] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-intrials-b99494132z1-303198321.html/.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 109 of 214. PageID #: 109

caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets."

315. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release.

316. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned because "it's in a very, very distinct area of the country."[202]

317. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for insufflation (snorting) using commonly available tools and methods" and "can [be readily] prepared for injection." It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

318. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, it also found that injection had become the preferred way of abusing the

[202] Tom Dreisbach et al., *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/healthshots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 110 of 214. PageID #: 110

drug.[203] However, and incredibly, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

319. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[204] The CDC specifically attributed the outbreak to the injection of Opana ER..[205]

b) New York's Investigation Found Endo Falsely Marketed Opana ER.

320. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[206] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

321. In October 2011, one month before the FDA's approval of reformulated Opana ER, Endo's director of project management e-mailed the company that developed the formulation technology for the drug to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

[203] *Id.*
[204] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://emergency.cdc.gov/han/han00377.asp (last visited Sept. 26, 2019).
[205] *Id.*
[206] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneidermanannounces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

> "*We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference* and this contributed to their statement that we had not shown an incremental benefit. *The chewing study (109) showed the same thing no real difference* which the FDA used to claim no incremental benefit."[207]

322. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract opioid from reformulated Opana ER than from the original version, and whether it would take longer to extract opioid from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

323. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company in which the consultant concluded that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant." The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[208]

324. Despite the results of Endo's own studies and the conclusions of Endo's director of project management and consultant, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[209]

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[207] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar. 1, 2016), (hereinafter "NYAG Endo Discontinuance") https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[208] *Id.*
[209] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 112 of 214. PageID #: 112

325. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary[210] committees of healthcare plans and PBMs misrepresented the Opana ER studies. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

326. According to Endo's Vice President for Pharmacovigilance and Risk Management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

327. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[211] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

328. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "Symptoms of withdrawal do not indicate addiction."[212] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the *Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition)*.

329. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as

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[210] A formulary is the official list of medicines that may be prescribed in a particular health care plan.
[211] NYAG Endo Discontinuance, *supra* n. 208.
[212] *Id*. at 7.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 113 of 214. PageID #: 113

a condition in which patients exhibit drug-seeking behavior that resembles, but is not the same as, addiction. However, Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the concept of pseudoaddiction.

c) Endo Funded False Publications and Presentations.

330. Like several of the other Manufacturing Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including the APF.

331. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled, "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[213]

332. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[214]

333. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

[213] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[214] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 114 of 214. PageID #: 114

334. Later, in 2014, Endo issued a patient brochure titled, "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

335. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
>
> - Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.[215]
>
> * * *

336. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled, "Screener and Opioid Assessment for Patients with Pain (SOAPP)

[215] Margo McCaffrey et al., *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 115 of 214. PageID #: 115

Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[216] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

337. Endo also sponsored the now-defunct website painknowledge.com, which was created by the APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[217] Among other featured content, painknowledge.com included a flyer titled, "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

338. Endo, along with Janssen and Purdue, also provided grants to the APF to distribute Exit Wounds, discussed above. *See supra* ¶ 97.

339. Endo also made thousands of payments to physicians nationwide, including to Chicago-area physicians, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

d) FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse.

340. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its

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[216] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf.

[217] *AboutPainKnowledge.org*, PainKnowledge, http://web.archive.org/web/20120119124921/ http://www.painknowledge.org/aboutpaink.aspx (last visited Dec. 14, 2018).

risks." According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder." Dr. Woodcock stated that if Endo did not comply with the request, the FDA would issue notice of a hearing and commence proceedings to compel its removal.

341. On July 6, 2017, Endo pulled Opana ER from the U.S. market.

e) Endo Failed to Monitor and Report Suspicious Sales as Required.

342. Opana ER has been widely prescribed in Illinois. According to data collected by ProPublica, during 2016, Illinois doctors' prescriptions of Opana ER to patients insured by Medicare Part D totaled more than $2 million.[218] On information and belief, and large number of those prescriptions were for patients from the Chicago area.

343. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

[218] ProPublica Prescriber Checkup, Opana ER, https://projects.propublica.org/checkup/drugs/1445.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 117 of 214. PageID #: 117

344. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

345. Endo failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also failed to report to the Board sales of suspicious drugs subject to abuse. Endo's failure to timely report these and other suspicious sales violated the CSA.

5. Cephalon.

346. Cephalon manufactures, markets, sells and distributes the following opioids in Chicago, in Illinois and nationwide:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain ("BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

347. According to public records compiled by ProPublica, in 2016 alone, Medicare Part D paid $1.1 million for claims arising from Illinois physicians' Fentora prescriptions.

348. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense breakthrough pain ("BTP")[219] in cancer patients. It delivers fentanyl citrate, a

[219] Breakthrough pain, or BTP, is an intense spike of pain experienced by some cancer patients

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 118 of 214. PageID #: 118

powerful opioid agonist that is 80 times stronger than morphine,[220] rapidly into a patient's bloodstream through the oral membranes.[221] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[222]

349. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[223]

350. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "*ONLY* for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[224] Further, the FDA explicitly stated that Actiq "*must not* be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain

when the pain exceeds the level which is controlled by chronic pain medications.

[220] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292 (hereinafter, "Carreyrou, *Narcotic Lollipop*").

[221] Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose.

[222] *Cephalon, Inc.*, Company-Histories.com, http://www.companyhistories.com/Cephalon-Inc-Company-History.html (last visited Dec. 14, 2018).

[223] 1998 FDA Label, https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20747_Actiq_appltr.pdf.

[224] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 119 of 214. PageID #: 119

specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

351. The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[225]

352. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

353. Cephalon also purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell Fentora as a faster-acting version of Actiq; but once again concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a) Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians.

354. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for revenue growth. In order to increase its revenue and market share, Cephalon needed to find a broader audience for the drug, and thus began marketing its opioid lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict

[225] Carreyrou, *Narcotic Lollipop*, *supra* n.220.

instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

355. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to market Actiq increased six-fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[226]

356. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[227] By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[228] By 2005, Actiq's sales total had jumped to $412 million, making it Cephalon's second-best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.

357. Although Actiq is a drug approved for only a very narrow customer base, during the first six months of 2006, only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[229]

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[226] *Id.*
[227] *Id.*
[228] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), http://getfilings.com/o0001047469-03-011137.html.
[229] Carreyrou, *Narcotic Lollipop*, *supra* n.220.

b) Government Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses.

358. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.[230]

359. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons.
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches.
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use.

[230] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 122 of 214. PageID #: 122

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication.

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl.

- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioidtolerant.[231]

360. Still, the letters, the FDA's safety alert, DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c) Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians.

361. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for noncancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

362. During an investor earnings call shortly after Fentora's launch, Cephalon's CEO described the "opportunity" presented by the use of Fentora for non-cancer pain:

> *The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain.*

* * *

[231] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. Nov. 21, 2006, at B1 (hereinafter, "Carreyrou, *Cephalon Used Improper Tactics*").

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 123 of 214. PageID #: 123

> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well-being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[232]

d) The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora.

363. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora and warned of death or life-threatening side effects. The FDA warned: Fentora should not be used to treat any type of short-term pain such as headaches or migraines, and that it should only be used under the close supervision of a doctor.[233]

364. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of noncancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that

[232] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call (May 1, 2007), http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript.
[233] FDA safety page: How to use Fentora safely, Drug Topics, https://www.drugtopics.com/fda/fda-safety-page-how-use-fentora-safely (last accessed Sept. 25, 2019).

the drug's safety for such use had never been clinically evaluated.[234] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

365. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

366. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

367. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

368. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled, "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited

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[234] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 125 of 214. PageID #: 125

indication, as detailed above, the first sentence of the insert stated: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[235]

e) Cephalon Funded False Publications and Presentations.

369. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were nonaddictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs and paying physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

370. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians in Illinois, Chicago, and across the country.

371. For example, a 2003 Cephalon-sponsored CME presentation titled, "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, stated:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming

[235] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 126 of 214. PageID #: 126

> addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[236]

372. Another Cephalon-sponsored CME presentation titled, "Breakthrough Pain: Treatment Rationale with Opioids" was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex regional pain syndromes, the neuropathies, and interstitial cystitis." (One slide from that CME presentation is set forth below). The presentation describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[237] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.

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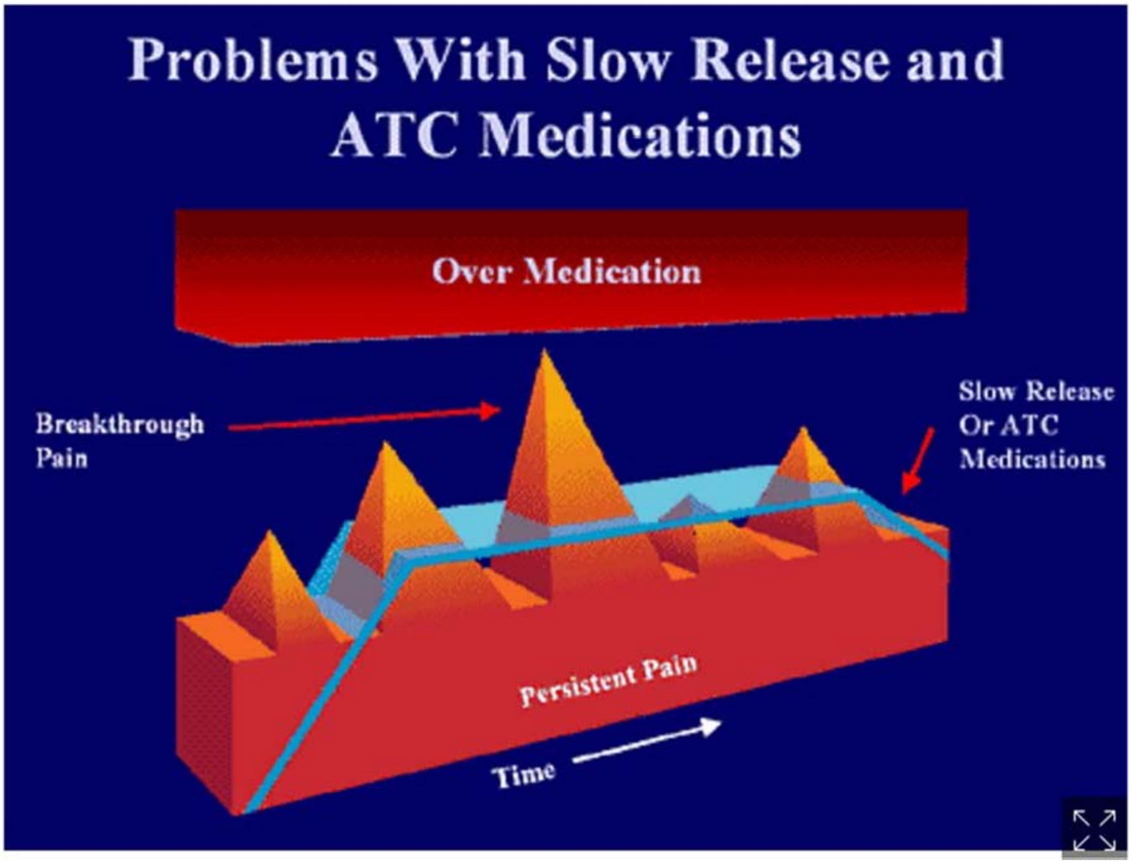
[236] Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, https://www.medscape.org/viewarticle/449803 (last visited Sept. 18, 2019).
[237] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, https://www.medscape.org/viewarticle/461612 (last visited Sept. 26, 2019).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 127 of 214. PageID #: 127



373. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled, "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate to treat migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated with high patient satisfaction ratings."[238] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

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[238] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), https://www.medscape.com/viewarticle/488337_2 (last visited Sept. 26, 2019).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 128 of 214. PageID #: 128

374. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines*.[239] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. *Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients*.[240]

375. Later in the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "*[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain*." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, *OTFC might also be used cautiously and safely for* acute pain experienced by *patients who are not opioid tolerant*. *Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant*. Examples include episodic pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[241]

376. Through its sponsorship of FSMB (*see supra* ¶¶ 78-88), Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

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[239] Gerald M. Aronoff et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).
[240] *Id.*
[241] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 129 of 214. PageID #: 129

377. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

378. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove titled, "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007 through December 15, 2008. The presentation stated that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.

379. Fine authored a Cephalon-sponsored CME presentation titled, "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report" supplement of the journal *Pain Medicine News* in 2009.[242] The CME presentation targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic

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[242] Perry G. Fine et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/view/11409251/opioid-basedmanagement-of-persistent-and-breakthrough-pain/9.

pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME presentation purported to analyze the "combination of evidence- and case-based discussions" and ultimately concluded:

> *All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected*[243]

380. Along with Purdue, Cephalon sponsored the APF's guide (*see supra* ¶¶97-108), which warned against the purported *under*-prescribing of opioids, taught that addiction is ***rare*** and suggested that opioids have "*no ceiling dose*" and are therefore the most appropriate treatment for severe pain. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continued, *"Pain management is a fundamental human right* in all patients not only with acute postoperative pain but also *in patients suffering from chronic pain*.".[244]

381. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[245]

382. In the March 2007 article titled, "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[246] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored

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[243] *Id.*
[244] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).
[245] *See* Chou, *Clinical Guidelines*, *supra* n.85.
[246] Donald R. Taylor et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 131 of 214. PageID #: 131

study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients."[247] The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cited Portenoy and recommended fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with *chronic noncancer pain* and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP *and the potential benefits of BTP-specific therapy* suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[248]

383. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. A single 2008 issue of the journal contained numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled, "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expressed disdain for the prior 20 years of opioid phobia.

384. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh stated: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and

[247] *Id.*
[248] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 132 of 214. PageID #: 132

that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[249]

385. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled, "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[250] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[251]

386. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." That article concluded that the number of abuse-related events was "small."[252]

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[249] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).
[250] Perry G. Fine et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).
[251] *Id.*
[252] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 133 of 214. PageID #: 133

387. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

388. Cephalon's payments to doctors have resulted in studies that support its sales but are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[253] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[254]

389. Teva, which acquired Cephalon, repeatedly refused to produce information requested as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent September 28, 2017, Senator McCaskill explained that "the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders." On March 6, 2018, Senator McCaskill issued a press release castigating Teva for its continued refusal to comply with her requests: "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide."[255] As of July 12, 2018, the date Senator McCaskill's third report

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[253] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.231.
[254] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).
[255] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, McCaskill: Teva Is Stonewalling a Senate Investigation (Mar. 6, 2018), https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation.

titled, *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, was published, Teva remained uncooperative.[256]

f) Cephalon Failed to Monitor and Report Suspicious Sales as Required.

390. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

391. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

392. Cephalon failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's failure to timely report these and other suspicious sales violated the CSA.

6. Insys

393. Insys manufactures, markets, sells and distributes the following pharmaceutical drug in Chicago, in Illinois and nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.	Schedule II

[256] *Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (July 12, 2018), https://www.hsgac.senate.gov/ imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf (hereinafter, "*July 2018 McCaskill Report*")

394. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[257] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

395. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. According to data collected by ProPublica, during the single year of 2016, Illinois doctors' prescriptions of Subsys to patients insured by the Medicare Part D program totaled more than $2.6 million. On information and belief, a large percentage of those prescriptions were for patients in the Chicago area. The majority of Insys' sales of Subsys are through wholesalers including AmerisourceBergen, McKesson and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys' total gross sales of Subsys, respectively.

[257] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 136 of 214. PageID #: 136

396. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[258]

397. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

398. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions.[259] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of *mild-to*-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[260] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

[258] Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC (Nov. 5, 2015, 10:13 AM), http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insyspharmaceuticals.html.
[259] *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015), https://www.documentcloud.org/documents/2195731-insysdoj.html.
[260] Portenoy's paper, "Breakthrough pain: definition, prevalence and characteristics," which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating'). . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 40(3) Pain 273-81 (July 1990).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 137 of 214. PageID #: 137

399. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[261]

a) Federal Investigation of Insys.

400. In 2018, the U.S. Department of Justice intervened in five lawsuits that were filed pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b), which alleged that Insys violated the Act due to its improper marketing practices of Subsys.[262]

401. In June 2019, Insys agreed to a settlement and deferred prosecution with the DOJ. It settled the civil cases for $195 million, and it agreed to pay a $2 million fine and $28 million in forfeitures, and plead guilty to five counts of mail fraud arising from kickbacks and bribes that were made as part of its illegal marketing practices.[263]

b) The Indictment of Insys Executives and the Arrest of Its Founder.

402. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[264]

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[261] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html.

[262] Settlement Agreement, available at https://www.justice.gov/usao-ma/press-release/file/1170131/download

[263] Press Release, Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019), https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal

[264] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 138 of 214. PageID #: 138

403. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a “reimbursement unit” at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and PBMs. Insys’ reimbursement unit employees were told to inform agents of insurers and PBMs that they were calling “from” or that they were “with” the doctor’s office, or that they were calling “on behalf of” the doctor.

404. The executive defendants in the indictment include John Kapoor (“Kapoor”), Insys’ former CEO and president, as well as the company’s former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. On October 26, 2017, Kapoor – the billionaire founder, CEO and chairman of Insys, who owns a 60% stake in the company – was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer.[265]

405. The charges against all seven executives include alleged violations of the federal Anti- Kickback Law, the Racketeer Influenced and Corrupt Organizations (“RICO”) statute and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers.

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ma/pr/pharmaceutical-executives-charged-racketeering-scheme (hereinafter, “Insys Indictment Press Release”); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, ECF. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter, “Insys Indictment”).

[265] Michela Tindera, *Opioid Billionaire Arrested On Racketeering Charges*, Forbes (Oct. 26, 2017), https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#14d33e606a00.

406. In May 2019, the defendants, including Kapoor and four top executives, were found guilty of conspiring to bribe doctors to prescribe Subsys.[266] They face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the defendants face a sentence of up to five years in prison and a $25,000 fine.

407. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

408. Harold H. Shaw ("Shaw"), special agent in charge of the FBI Boston field division, said in a statement, "[a]s alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers."[267]

c) Insys Targeted Non-Cancer Treating Physicians and Funded False Publications and Presentations.

409. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires,

[266] Press Release, U.S. Attorney's Office for the District of Massachusetts, Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy, https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy.
[267] Press Release, U.S. Department of Justice, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering, https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 140 of 214. PageID #: 140

employing sales representatives and other employees at practitioners' behest and with the expectation that such hires would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

410. Specifically, in June 2012, former executives began using in-person meetings, telephone calls and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[268]

411. Speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

412. Insys made thousands of payments to physicians nationwide, including to Chicago-area physicians, for participating on these speakers' bureaus and for other services.

413. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain.

414. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

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[268] Insys Indictment, *supra* n.266, ¶ 38.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 141 of 214. PageID #: 141

> These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug.[269]

415. The indictment also alleges that, when agents of insurers or PBMs asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."[270]

416. Insys' former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

417. In a press release issued when the indictment was announced, Shaw, the FBI Special Agent in charge of the Boston Field Division, linked the allegations to the national opioid epidemic:

> *As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life*

[269] *Id.* ¶ 50.
[270] *Id.* ¶ 180.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 142 of 214. PageID #: 142

> *threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts.*[271]

418. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "Causing the unnecessary use of opioids by current and retired U.S. military service members shows disregard for their health and disrespect for their service to our country . . . ."[272]

419. On August 31, 2017, Arizona Attorney General Mark Brnovich filed a lawsuit alleging violations of the Arizona Consumer Fraud Act of 1967 ("ACFA") by Insys, two of its former employees and three doctors. Attorney General Brnovich alleged that Insys and its two named employees – former Vice President of Sales Alec Burlakoff and former Manager of Reimbursement Services Elizabeth Gurrieri – engaged in numerous deceptive or unfair acts and practices, including those related to:

- the use of the Insys Reimbursement Center ("IRC"), which was designed to obtain prior authorization for Subsys from insurers and PBMs, misleading consumers about the prior authorization process and the IRC's practices;
- failing to warn consumers about IRC practices, even though Insys knew or had reason to know that healthcare professionals using the IRC would not be in a position to reduce foreseeable risks of harm due to the IRC's practices;
- providing healthcare professionals with false and misleading information, and concealing, suppressing or omitting material facts about the definition of "breakthrough cancer pain" and the FDA-approved uses of Subsys, in order to deceive healthcare professionals so that they would prescribe more Subsys;

[271] *Id.*
[272] *Id.*

- failing to warn consumers of the foreseeable risks of harm from Subsys and Insys' practices while knowing or having reason to know that healthcare professionals to whom Insys provided false and misleading information would not be in a position to reduce the foreseeable risks of harm; and
- providing sham "speaker fees" to healthcare practitioners to induce, and in exchange for, the healthcare practitioners writing Subsys prescriptions.

420. According to the complaint, between March 2012 and April 2017, the three defendant doctors wrote more than $33 million worth of Subsys prescriptions while being paid, on average, approximately $200,000 each in "speaker fees" by Insys.

421. According to the complaint, in order to be booked as speakers and receive speaker fees, doctors were required to have at least 20 patients on Subsys. On the other hand, frequent prescribers of Subsys were "rewarded" by being paid in speakers fees, which served to "notice[]" "their support of Subsys" with "positive reinforcement."

422. On April 13, 2018, the DOJ, joined by the states of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Massachusetts and Virginia, and the District of Columbia, filed a False Claims Act complaint against Insys, focusing on illegal kickbacks to doctors.

423. Similar to the claims in the ACFA litigation, the DOJ alleged: Since 2012, Insys has operated a "speaker program" through which it has paid Subsys prescribers to give speeches about Subsys to physicians and other healthcare professionals. Insys has pretended that these presentations were intended to provide potential Subsys prescribers with substantive medical information about the drug. In reality, many of these events have been mere pretexts for paying thousands of dollars in sham speaking fees to prescribers for the purpose of inducing them to prescribe Subsys. Many of these speeches have been attended only by the prescriber's own office staff, by close friends who attended multiple presentations, or by people who were not medical

professionals and had no legitimate reason for attending. Many of the "speeches" have not involved any actual substantive presentation by the purported "speaker." The events have often been held in expensive restaurants.[273]

d) Insys Failed to Monitor and Report Suspicious Sales as Required.

424. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

425. Insys is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

426. Insys failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Insys' failure to timely report these and other suspicious sales violated the CSA.

7. Mallinckrodt

427. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in Chicago, in Illinois and nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

428. Among the drugs it distributes are the following:

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[273] Complaint, *United States of America, et al. v. Insys Pharma., et al.*, No. 13-cv-05861 (C.D. Cal. Apr. 13, 2018) https://www.justice.gov/opa/press-release/file/1063051/download.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 145 of 214. PageID #: 145

Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.*, non-opioid analgesics) are inadequate. The FDA approved the 8, 12 and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.	Schedule II
Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues and stars.	Schedule II
Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.	Schedule II
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.	Schedule II
Morphine sulfate extended release	Generic product.	Schedule II
Fentanyl extended release	Generic product.	Schedule II
Fentanyl citrate	Generic product.	Schedule II
Oxycodone and acetaminophen	Generic product.	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic product.	Schedule II
Hydromorphone hydrochloride	Generic product.	Schedule II
Hydromorphone hydrochloride extended release	Generic product.	Schedule II
Naltrexone hydrochloride	Generic product.	Schedule II
Oxymorphone hydrochloride	Generic product.	Schedule II
Methadone hydrochloride	Generic product.	Schedule II
Oxycodone hydrochloride	Generic product.	Schedule II

429. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[274]

a) Mallinckrodt Funded False Publications and Presentations.

430. Like the other Manufacturing Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations that disseminated false messaging about opioids.

431. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[275]

432. Among other content, the website included a handout titled, "Oxycodone Safety Handout for Patients," which advised practitioners that "[p]atients' fears of opioid addiction should be dispelled."[276] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?
>
> - After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
> - This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[277]

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[274] *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012), http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE.

[275] *Pain Treatment Topics*, Pain-Topics.org

[276] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

[277] *Id*.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 147 of 214. PageID #: 147

433. Additionally, the FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain are very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudo addiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[278]

434. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[279] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[280]

[278] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20080630030443/http://pain-topics.org/faqs/index1.php#tolerance (last visited Oct. 1, 2019).
[279] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, The Intercept (Apr. 4, 2017, 2:15 PM), https://theintercept.com/2017/04/04/scott-gottlieb-opioid/.
[280] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 148 of 214. PageID #: 148

435. Mallinckrodt also made thousands of payments to physicians in Chicago, in Illinois and nationwide.

b) The DEA Investigates Suspicious Orders.

436. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report – suspicious orders for its generic oxycodone between 2008 and 2012.[281] The U.S. Attorney's office in Detroit handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[282] According to the internal government documents obtained by the *Washington Post*, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[283]

437. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise") of Broward County, Mallinckrodt, in the following six weeks, sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 to a single patient.[284]

438. Mallinckrodt's aggressive sales efforts continued unabated even as it was being investigated. In 2009, national account manager Victoria Borelli acknowledged in an email to Steve Cochrane, vice president of sales for KeySource Medical, a distributor: Borelli urged

[281] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?hpid=hp_hp-top-table-main_dea-645pm%3Ahomepage%2Fstory&utm_term=.c3c7673e35de.
[282] *Id.*
[283] *Id.*
[284] *Id.*

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 149 of 214. PageID #: 149

Cochrane to check his inventories and "[i]f you are low, order more. If you are okay, order a little more, Capese?" She then joked, "destroy this email." In another email in January 2009, Borelli told Cochrane that 1,200 bottles of oxycodone 30 mg tablets had been shipped, to which Cochrane responded. "Keep 'em comin'!" "Flyin; out of there. It's like people are addicted to these things or something. Oh, wait, people are…" Borelli responded: "Just like Doritos keep eating. We'll make more."[285]

439. According to documents obtained by the *Washington Post*, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those violations included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[286]

440. In May 2014, Mallinckrodt posted a video titled, "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis, McKesson, Mallinckrodt, AmerisourceBergen and Qualitest – all of whom are conveniently missing from the list of those responsible.[287]

441. In April 2017, Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Michigan and Northern District of New York to pay $35

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[285] Scott Higham, Sari Horwitz, and Steven Rich, *Internal drug company emails show indifference to opioid epidemic*, Washington Post (July 19, 2019) (hereinafter "Internal drug company emails"), https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html?utm_term=.a3f264b7138e.
[286] *Id.*
[287] National Association of Boards of Pharmacy, *Red Flags*, YouTube (May 20, 2014), https://www.youtube.com/watch?v=WY9BDgcdxaM.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 150 of 214. PageID #: 150

million to resolve a probe of its distribution of its opioid medications.[288] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[289]

c) Mallinckrodt Failed to Monitor and Report Suspicious Sales as Required.

442. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

443. Mallinckrodt is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

444. Mallinckrodt failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Mallinckrodt's failure to timely report these and other suspicious sales violated the CSA.

8. Actavis.

445. Actavis manufactures, markets, sells and distributes pharmaceutical drugs in Chicago and nationwide. Until it sold its portfolio of generic opioids to Teva, Actavis was among the largest U.S. suppliers of opioid pain medications.

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[288] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, AP News (Apr. 3, 2017), https://www.apnews.com/28dbac05ce924d0a8b710b8ea55df5db.
[289] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 151 of 214. PageID #: 151

446. Among the drugs Actavis distributes or distributed during the times relevant to the allegations herein are the following:

Kadian (morphine sulfate, extended release)	Opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. 20 mg, 50 mg and 100 mg strengths approved by the FDA in 1996. 30 mg and 60 mg strengths approved by the FDA in 2001. 80 mg strength approved by the FDA in 2006. 10 mg and 200 mg strengths approved by the FDA in 2007. 40 mg, 70 mg, 130 mg and 150 mg strengths approved by the FDA in 2012.	Schedule II
Norco (hydrocodone bitartate and acetaminophen)	Opioid agonist initially indicated for the relief of moderate to moderately severe pain. Later, indication amended to treat acute pain severe enough to require opioid analgesic and for which alternative treatments are inadequate. Norco was initially approved by the FDA in 1997.	Schedule III (1997-2014) Schedule II (2014-present)
Oxymorphone hydrochloride	Generic equivalent of Opana ER. Launched in 2013.	Schedule II
Morphine sulfate extended- release	Generic equivalent of Kadian. Launched in 2013.	Schedule II
Fentanyl citrate transdermal patch	Generic equivalent of Duragesic. Launched in 2007.	Schedule II

447. Actavis acquired Kadian from King Pharmaceuticals in 2008 for an amount up to $127.5 million, depending on quarterly sales-related milestones.

448. Actavis marketed and sold generic opioids until it sold its generic opioid portfolio for $40.5 billion to Teva in 2016.

a) The FDA Issued a Warning Letter to Actavis Concerning Extensive False and Misleading Claims in Kadian Marketing Materials.

449. On February 18, 2010, the FDA's Division of Drug Marketing, Advertising, and Communications issued a warning letter ("2010 Warning Letter") to Actavis concerning the marketing of Kadian. The letter warned that certain marketing materials for Kadian "are false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present

unsubstantiated superiority and effectiveness claims" in violation of the FDCA and regulations promulgated thereunder. Specifically, the 2010 Warning Letter addressed two marketing materials: a Comparison Detailer and a Co-Pay Assistance Program brochure.

450. According to the 2010 Warning Letter, the marketing materials "present several effectiveness claims for Kadian but fail to present any contraindications, and also omit several warnings, precautions, drug interactions and adverse events" including by failing to include "warnings regarding potentially fatal abuse of opioids [and] use by individuals other than the patient for whom the drug was prescribed."

451. The 2010 Warning Letter also states that the Comparison Detailer "fails to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information." Whereas "the first five of the six pages of the Comparison Detailer prominently present efficacy claims about Kadian using large, bolded headers and claims surrounded by a significant amount of white space . . . using colorful charts and graphs," "the only specific risk information presented is relegated to the back cover . . . in a small font . . . beneath a large, bolded headline claim that presents a benefit claim."

452. The 2010 Warning Letter provides that the effect of these presentations "minimizes the risks associated with Kadian and misleadingly suggests that Kadian is safer than has been demonstrated."

453. Further, the 2010 Warning Letter states that Kadian promotional materials were misleading because they "present broad claims about the drug's use in treating pain, therefore implying that Kadian is appropriate for use in a broader range than it is approved to treat." The 2010 Warning Letter cites the following examples from the Comparison Detailer:

- "Allow for less breakthrough pain and more consistent pain relief for patients."

- “Better pain control . . . .”
- “Improved pain control . . . .”
- “Allow patients to live with less pain . . . .”
- “Less Pain. More options.”

454. According to the 2010 Warning Letter, “[t]hese presentations in the Comparison Detailer suggest that Kadian is appropriate for patients with broader types of pain than the drug is indicated for.”

455. The 2010 Warning Letter found similar problems in the Co-Pay Assistance Program brochure, which included the following statements (emphases in original):

- “**Why is pain management important?** Pain management is a large part of your overall health care plan. Many Americans suffer from chronic or ongoing pain . . . Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse.”
- “**What is chronic pain?** Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe. . . .”
- “**How can I treat my chronic pain?** To help manage your pain, your healthcare provider will determine what level of pain control you need. Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you.”

456. The 2010 Warning Letter states that these statements “suggest[] that patients with broader types of chronic pain than the drug is indicated for are appropriate candidates for Kadian therapy, when this is not the case. . . . Kadian is *only* appropriate for a very limited patient population who experience pain.” (Emphasis in original.) It continues, “[i]n addition, the partial indication included on the back cover of the Co-Pay Assistance Program brochure, unlike the chronic pain information, is written in technical medical language that is not likely to be easily understood by consumers.”

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 154 of 214. PageID #: 154

457. Next, the 2010 Warning Letter identifies unsubstantiated superiority claims, including that Kadian "[a]llow[s] for less breakthrough pain and more consistent pain relief for patients" and asks, "Why settle for generic MS Contin tablets . . . When you can prescribe the benefits of KADIAN capsules?" According to the Letter, these "claims and presentations misleadingly imply that Kadian has been shown to be superior to MS Contin or generic controlled-release morphine" but the "FDA is not aware of ***any*** substantial evidence or substantial clinical expertise that supports these claims and presentations." (Emphasis in original.)

458. The 2010 Warning Letter also identifies the following claims "supported by a historically controlled study of inadequate design, completely lacking any concurrent control"; "[b]etter pain control and improved sleep scores"; "[i]mproved pain control and sleep scores in patients treated with KADIAN who were previously on CR morphine tablets"; and "[a]llow patients to live with less pain and get adequate rest with less medication." The 2010 Warning Letter states that the trial identified in support of these claims "clearly do[es] not support any conclusion that Kadian is superior to alternative treatments in pain or sleep measures."

459. Further, the 2010 Warning Letter focuses on the Comparison Detailer's inclusion of dosing claims comparing Kadian with MS Contin and Avinza. The Detailer claims that Kadian presents "[f]ewer barriers to prescribing" because "[t]he unique dosing flexibility of KADIAN gives you more options with morphine" than does MS Contin or Avinza. However, "the FDA is unaware of any substantial evidence or substantial clinical experience to support the claim that the above dosing characteristics allow Kadian to have 'fewer barriers to prescribing' (the meaning of which is not clear) as compared to other extended-release morphine products."

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 155 of 214. PageID #: 155

460. In conclusion, the 2010 Warning Letter found that the Comparison Detailer and Co-Pay Assistance Program brochure "misbrand Kadian in violation of the [FDCA]."

b) Actavis Failed to Monitor and Report Suspicious Sales as Required.

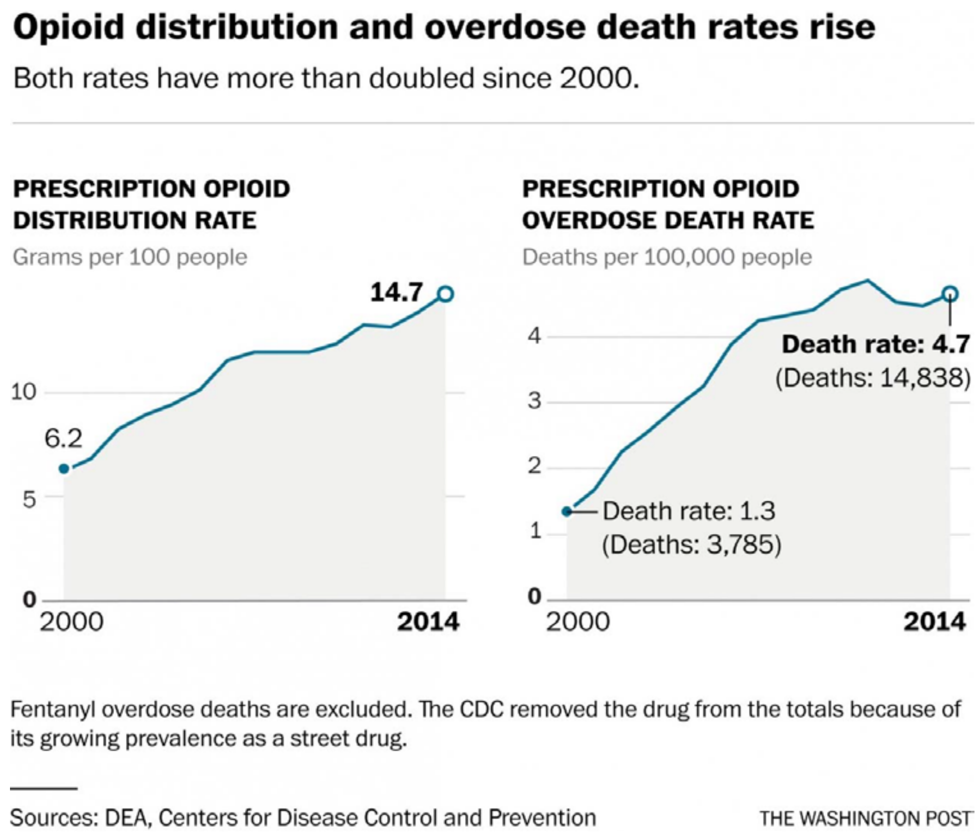
461. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

462. Actavis is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

463. Actavis failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Actavis's failure to timely report these and other suspicious sales violated the CSA.

D. The Distributor Defendants Failed to Track and Report Suspicious Sales as Required by Federal Law.

464. Manufacturers rely upon wholesale distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



465. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent Joe Rannazzisi ("Rannazzisi"), who blamed the Distributor Defendants for killing people by violating the CSA requirement to report suspicious orders:

> **RANNAZZISI**: This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.
>
> * * *
>
> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.
>
> **[INTERVIEWER]**: Who are these distributors?
>
> **RANNAZZISI**: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 157 of 214. PageID #: 157

> **[INTERVIEWER]**: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **RANNAZZISI**: That's not an implication, that's a fact. That's exactly what they did.[290]

466. Jim Geldhof ("Geldhof"), a 40-year veteran of the DEA who ran investigations in the Detroit field office, corroborated Rannazzisi's account, saying that the wholesalers are "absolutely" responsible for the opioids epidemic:

> **[INTERVIEWER]**: These companies are a big reason for this epidemic?
>
> **GELDHOF**: Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.[291]

1. McKesson.

467. McKesson, headquartered in San Francisco, is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical drug distributor in the United States. It distributes pharmaceuticals through a network of distribution centers across the country, including in Elgin, Illinois and Glendale Heights, Illinois, which are both suburbs of Chicago.[292] McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

468. McKesson supplies various United States pharmacies an increasing amount of prescription opioids, products frequently misused that are at the heart of the current opioid epidemic.

[290] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Jun. 17, 2018), https://www.cbsnews.com/news/60-minutes-ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.
[291] *Id*.
[292] McKesson.com, Medical Distribution, https://mms.mckesson.com/content/our-story/distribution-services/#nationwide.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 158 of 214. PageID #: 158

469. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

470. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

471. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its new or existing customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

472. In 2011, McKesson's then-director of regulatory affairs, David B. Gustin, told his colleagues that he was concerned about the "number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy … and the amount they really need

… This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be used for legitimate purposes."[293]

473. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys General built a case against McKesson for the company's role in the opioid crisis, which David Schiller ("Schiller"), then Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."[294]

474. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> **SCHILLER**: If they woulda stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> **[INTERVIEWER]**: And they had none.

[293] Internal drug company emails, *supra* n.285.
[294] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

> **SCHILLER**: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[295]

475. Indeed, according to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012, in violation of the company's settlement with the DOJ, and never fully implemented or followed the monitoring program required under the terms of the settlement to which it agreed.

476. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law. As part of the 2017 agreement, McKesson acknowledged:

> at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.[296]

2. Cardinal Health.

477. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over $121 billion.

478. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter and consumer products in the United States. Of

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[295] *Id.*
[296] McKesson Settlement Agreement and Release, 5, https://www.justice.gov/opa/press-release/file/928471/download.

Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

479. Cardinal Health distributes pharmaceuticals through a network of distribution centers across the country, including distribution centers in Aurora and Waukegan, Illinois, both in the metropolitan Chicago area. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue. According to its website, CVS operates 70 pharmacies in Chicago.[297]

480. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq*. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

481. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.[298]

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[297] CVS Store Locator, https://www.cvs.com/store-locator/cvs-pharmacy-locations/Illinois (last accessed July 23, 2019).

[298] Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012, certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes. Press Release: Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act, https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 162 of 214. PageID #: 162

482. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and
- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

483. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder"). In the press release, Colder confirmed that the settlement primarily concerned the opioid oxycodone:

> DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . . . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety . . .[299]

3. AmerisourceBergen.

484. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States through a network of 26 pharmaceutical distribution centers, including one in Romeoville, Illinois, a

[299] *Id.*

suburb of Chicago.[300] It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

485. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq*. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

486. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[301] AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period. Moreover, public documents also demonstrate that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West

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[300] *AmerisourceBergen*, Wikipedia, https://en.wikipedia.org/wiki/AmerisourceBergen (hereinafter, "*AmerisourceBergen*") (last visited July 23, 2019).

[301] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/legal_affairs/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 164 of 214. PageID #: 164

Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

E. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

487. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

488. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

489. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Summit County in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

1. The National Retail Pharmacies Have a Duty to Prevent Diversion

490. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal

market by, among other things, monitoring, and reporting suspicious activity.

491. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

492. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

493. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

494. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 166 of 214. PageID #: 166

and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

495. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

496. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

497. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

498. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

499. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

500. Upon information and belief, this problem was compounded by the Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 167 of 214. PageID #: 167

into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

501. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

502. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

503. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

504. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

505. The National Retail Pharmacies were, or should have been, fully aware that the

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 168 of 214. PageID #: 168

quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Multiple Enforcement Actions Against The National Retail Pharmacies Confirms their Compliance Failures

506. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a) CVS

507. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

508. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

509. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney’s Office for the Eastern District of California regarding allegations that its pharmacies

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 169 of 214. PageID #: 169

failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

510. The fine was preceded by numerous others throughout the country.

511. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

512. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

513. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

514. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

515. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

516. In May 2015, CVS agreed to pay a $22 million penalty following a DEA

investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

517. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

518. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

519. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b) Walgreens

520. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

521. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 171 of 214. PageID #: 171

and other prescription painkillers to be diverted for abuse and illegal black market sales.

522. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

523. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

524. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

525. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010,

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 172 of 214. PageID #: 172

Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

526. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

527. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

528. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

529.

F. Chicago Public School District.

1. Defendants Targeted Their Efforts at Marketing and Distributing Opioids at Chicago and the Surrounding Areas.

530. Defendants employed the same marketing plans and strategies and deployed the same messages in the Chicago area as they did nationwide.

531. As they did nationwide, Defendants extensively tracked the prescribing behavior of Chicago-area health care providers and used that data to target their detailing and speaker-recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and

dose) product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

532. This information allowed Defendants to target, within each sales territory, prescribers who could have the biggest sales impact. Indeed, one Chicago pain specialist surveyed by the City of Chicago estimated that he writes 600-700 opioid prescriptions each month for the treatment of long-term chronic pain, observed that detailers see him often because he is "big money for these people."

533. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain, and were part and parcel of Defendants' marketing campaigns in the Chicago area.

534. A survey of Midwest prescribers and interviews of Chicago providers and prescribers reveal that each Defendant made misrepresentations to prescribers via detailing visits, CMEs, small-group speaker programs, dinners, and other events; branded advertisements; and unbranded promotional materials funneled through third parties. These deceptive and unfair messages include unfounded and untrue claims that long term opioid use for chronic pain could lead to functional improvements, that certain medications (such as OxyContin) provided 12-hours of pain relief, and that opioids were superior to NSAIDs for long term pain treatment. These messages downplayed or outright denied the risks of abuse, addiction, withdrawal, and overdose.

535. The Center for Medicare and Medicaid Services reports that 1,288,031 Medicaid claims were made in Illinois in 2017 alone.[302] On information and belief, a large percentage of those claims were made by Chicago residents, including students of CPS.

[302] Medicaid State Opioid Prescribing Map, CMS, https://cms-oeda.maps.arcgis.com/apps/MapSeries/index.html?appid=a0c111f23bf44077838a1cb889b7a6a3.

536. The following is a non-exhaustive list of misrepresentations and deceptive messaging that Defendants delivered to Chicago-area prescribers.

537. **Activis made misrepresentations to Chicago-area prescribers.**

538. Activis sales representatives and speakers were directed to, and did, visit potential prescribers in Chicago, as elsewhere, to deliver their deceptive messages. Activis tracked, in substantial detail, the prescribing behavior of Chicago area physicians. Chicago prescribers have recounted that Actavis detailers omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs, and overstated the benefits of opioids, including by making claims of improved function. Activis distributed these messages, or facilitated their distribution, in Chicago with the intent that Chicago prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

539. A survey of Midwestern physicians documented that Kadian sales representatives promoted Kadian as being less addictive than other Schedule II opioids at least between 2006 and 2008. In addition, in interviews with the City, Chicago-area prescribers reported hearing similar claims from Activis, and most of those prescribers did indeed prescribe opioids.

540. Most of the providers who received these misstatements did, in fact, prescribe Activis's opioids. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

541. **Cephalon made misrepresentations to Chicago-area prescribers.**

542. Cephalon targeted Chicago prescribers by recruiting them for its speakers bureaus to market Actiq and Fentora. Cephalon's speakers regularly held talks for Chicago prescribers, where it distributed misleading messages, including that doctors would be punished for failing to

prescribe opioids to their patients with pain. Cephalon distributed these messages, or facilitated their distribution, in Chicago with the intent that Chicago prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

543. Cephalon sponsored a publication by APF—which reached Chicago providers—entitled Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids differ from NSAIDs in that they have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the real number is closer to 3,000.

544. Cephalon developed a guidebook, which was intended to reach Chicago prescribers, called Opioid Medications and REMS: A Patient’s Guide, which deceptively minimized the risks of addiction from the long-term use of opioids. The book claimed that “patients without a history of abuse or family history of abuse do not commonly become addicted to opioids.”

545. Cephalon also targeted prescribers through use of its sales force. For instance, in planning for its launch of Fentora, a drug whose sole indication is to treat cancer pain, Cephalon hosted at least 10 events, meeting with 151 prescribers in Chicago through speakers bureau programs and dinners during the fourth quarter of 2006. Cephalon spent over $200,000 on these meetings, many of which were the prescribers who did not specialize in treating cancer patients. Cephalon knew that its purpose in meeting with these Chicago prescribers was to promote off-label use.

546. A survey of Midwest physicians and City of Chicago interviews of Chicago-area prescribers confirms that Cephalon made deceptive statements about the use of its drugs Actiq

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 176 of 214. PageID #: 176

and Fentora, including that they were appropriate for treating long term chronic pain, and minimized or omitted discussions of the drugs' potentials for abuse and addiction.

547. Most of the providers who received these misstatements did, in fact, prescribe Cephalon's opioids. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

548. **Endo made misrepresentations to Chicago-area prescribers.**

549. Endo directed and disseminated misstatements about its opioid drugs to Chicago patients and prescribers, including through its sales force, speakers' bureaus, CMEs, and the website Painknowledge.com, which was run by Endo-sponsored National Initiative on Pain Control. Endo distributed these messages, or facilitated their distribution, in Chicago with the intent that Chicago prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

550. Endo sales representatives delivered deceptive messages to Chicago prescribers. A former Endo sales representative who marketed Endo drugs Opana and Opana ER in Chicago's southwest suburbs, including Joliet, Orland Park, and Tinley Park, has admitted to representatives of the City of Chicago that she was not trained in the risks of long-term opioid use and she would dodge any questions about addiction in her meetings with physicians. She targeted physicians who prescribed NSAIDs and Vicodin to persuade them to switch to Opana ER, wrongly claiming that Opana ER would improve their ability to function. Finally, she distributed Endo-sponsored written materials to physicians, which misleadingly implied that pain patients would not become addicted to opioids over the long term.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 177 of 214. PageID #: 177

551. In a survey of Midwest physicians and interviews with Chicago-area prescribers, prescribers by the City of Chicago confirm that Endo sales people omitted or minimized the risks of opioid addiction; claimed the Endo's drugs would be less problematic for patients because they were tamper resistant and "difficult to abuse"; claimed or implied that they were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

552. Most of the providers who received these misstatements did, in fact, prescribe Endo's opioids. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

553. **Janssen made misrepresentations to Chicago-area prescribers.**

554. Janssen directed misstatements about its opioid drugs to Chicago patients and prescribers, including through CMEs, its sales force, recruited physician speakers, and third parties. Janssen did so with the intent that Chicago prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

555. Janssen sponsored CMEs and talks attended by Chicago prescribers. From 2009 to 2013, Janssen spent over $195,000 on 103 speakers bureau programs in Cook County, retaining 27 different physicians as speakers (including four or the top six Nucynta prescribers in Chicago) who gave talks with more than 1,000 attendees.

556. Speakers on Janssen's bureau were among the most prolific prescribers of Janssen's opioids.

557. In a survey of Midwest physicians and City of Chicago interviews with Chicago-area prescribers, prescribers report that Janssen detailers claimed Nucytna was "not an opioid"

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 178 of 214. PageID #: 178

because it worked on an "alternate receptor;" claimed that Janssen's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on Janssen's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

558. Most of the providers who received these misstatements did, in fact, prescribe Janssen's opioids. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

559. **Purdue made misrepresentations to Chicago-area providers.**

560. Purdue directed the dissemination of misstatements regarding its opioid drugs to Chicago patients and prescribers through Front Groups, KOLs, and publications, as well as through its substantial sales force in Chicago and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

561. Purdue disseminated the false statement that OxyContin provided 12 hours of pain relief directly to Chicago prescribers surveyed by the City of Chicago.

562. Prescribers interviewed by the City of Chicago reported receiving messages and/or omissions regarding addiction and the potential for abuse from Purdue sales representatives that were deceptive. The messages included that Purdue's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof, and

were "steady state." Sales reps claimed that OxyContin would provide 12 hours of pain relief; represented that screening tools could help manage the risk of addiction, minimized the symptoms of withdrawal, claimed or implied that opioids were safer than NSAIDs, and overstated the benefits of opioids, including that they improve function. A survey of Midwest physicians reported receiving messages from Purdue detailing visits and other doctors reported receiving the same or similar misrepresentations about Purdue opioids.

563. Most of the providers who received these misstatements did, in fact, prescribe Purdue's opioids. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

2. As a result, Chicago Public Schools Has Been Damaged.

564. Like the rest of the nation, the students, parents and staff of the Plaintiff have been severly injured by the opioid epidemic. And children born to opioid-addicted parents are perhaps the most faultless victims of the epidemic, with their lives permanently impaired by addiction from time in utero. Approximately 75 to 90 percent of children exposed to opioid use in the womb are born with Neonatal Abstinence Syndrome (NAS).[303] NAS is essentially the process of the newborn infant going through withdrawal from the *in utero* drug addiction, and it is a condition that is accompanied by serious and often chronic developmental disabilities. A disproportionate number of these children require enhanced educational services, including, but not limited to special education programs.

565. In a Tennessee study, children with a history of NAS were found to be significantly more likely to develop an educational disability and be eligible for special

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[303] Denise J. Maguire, et al., Long-Term Outcomes of Infants with Neonatal Abstinence Syndrome, 35 Neonatal Network 5 (2016).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 180 of 214. PageID #: 180

education services when compared with children who had no history of NAS. The study found that a significantly higher proportion of children with a history of NAS were diagnosed with educational disabilities of developmental delay and speech and language impairment, and a significantly higher number of students with NAS received therapies or services than those without a history of NAS.[304]

566. At the beginning of 2018, CPS had approximately 50,772 students who qualified for special education, which it is required by state and federal law to provide. Special education students accounted for approximately 14.1 percent of the total student population.

567. CPS has observed that an increase in students who qualify for special education services in its district correlates with the rise of opioid addiction nationwide. Plaintiff has documented a significant increase of approximately 1500 students, or two percent of its total students, in those who qualify for special education services between 2010 and 2019, with the percentage of students rising steadily each year. In those same years, Plaintiff has documented a 3.8 percent increase in the proportion of students who qualify for special education services by the twentieth day of kindergarten.[305] Notably, this increase in the proportion of special education students occurred during a time when the District's population was steadily declining each year.

568. CPS is required by state and federal law to make considerable expenditures to accommodate and educate students with special learning needs. For instance, extra personnel are required to educate special education students. Pursuant to state law, classrooms serving exclusively special education students who receive those services more than 60 percent of the

[304] Mary-Margaret A. Fill, et al., Educational Disabilities Among Children Born with Neonatal Abstinence Syndrome, 142 Pediatrics 3 (2018), https://pediatrics.aappublications.org/content/142/3/e20180562.
[305] Chicago Public Schools, School Data, Demographics, https://cps.edu/SchoolData/Pages/SchoolData.aspx.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 181 of 214. PageID #: 181

school day are capped at 8 students, with two additional students allowed if a paraprofessional is present at all times. Where a special education student receives services in a separate classroom less than 60 percent of the school day, state law limits the class size to 10 or 15 students.[306] Approximately 4 percent of students receiving special education services required a separate facility to meet the minimum standard for a free and appropriate public education.

569. CPS expends resources to screen for special education needs in early childhood. Through its Child Find program, CPS provides free early childhood developmental screenings for children birth to age 5 who reside within the city limits. CPS's Office of Early Childhood Education then collaborates with the City of Chicago Department of Family and Support Services to provide services for children identified as having developmental delays in community-based childcare facilities throughout the city.

570. The number of children removed from their homes and sent to foster care due to drug use has increased during the opioid epidemic. Since 2005, the percentage of foster care removals that were attributable to parents using drugs doubled from 15 percent in 2005 to 36 percent in 2017.[307] Additionally, the link between opioid use disorder and homelessness has been conclusively established, and youth are particularly vulnerable to becoming homeless because of opioid use disorder and misusing opioids once they become homeless.[308]

571. CPS's Department of Students in Temporary Living Situations provides services to its nearly 15,000 homeless students. Services include free transportation to the school that the

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[306] 23 Illinois Administrative Code 226.730.

[307] Dennis Thompson, *Kids Sent to Foster Care Doubles Due to Opioids*, WedMD (Jul. 15, 2019), https://www.webmd.com/mental-health/addiction/news/20190715/opioid-epidemic-doubled-number-of-us-kids-sent-to-foster-care#1.

[308] U.S. Dept. of Health and Human Servs. Assistant Sec. for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy, *Choice Matters: Housing Models that May Promote Recovery for Individuals and Families Facing Opioid Use Disorder*, iv, 4 (June 2019), https://www.abtassociates.com/sites/default/files/files/Insights/reports/2019/Choice.pdf.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 182 of 214. PageID #: 182

child attended when he or she became homeless, free uniforms, fee waivers, counseling services, and social work services. For children sixth grade and under, CPS also provides free transportation to their parent.

572. CPS provides insurance benefits to more than 37,000 employees. As part of its benefits package, CPS has paid for more than 6.7 million units of prescription opioids for its employees between the years of 2013-2018. Upon information and belief, many of these prescription opioids were inappropriately prescribed to treat chronic pain.

V. CLASS ALLEGATIONS.

573. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of

a. Nationwide Class:

All independent public school districts nationwide.[309]

b. Illinois Sub-Class

All public school districts in the State of Illinois.[310]

574. Plaintiff is a member of both Classes it seeks to represent.

575. The proposed class definitions are intended to be subject to revision if facts adduced in discovery suggest desirable or necessary refinements to it, including but not limited to the addition of subclasses, if appropriate.

[309] Unless otherwise specified, references to "the Class" in this complaint refer to both the Illinois and Nationwide Classes.
[310] As noted in footnote 6, all of the public schools in Illinois are independent units of government.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 183 of 214. PageID #: 183

576. The members of each of the Classes are sufficiently numerous that joinder of all members is impracticable. Plaintiff is informed and believes that there are 852 members of the Illinois Sub-Class and 12,884 members of the Nationwide Class.[311]

577. Questions of fact and law common to the Classes are both well-suited to class-wide adjudication and predominate over any questions affecting only individual class members. These common, predominating questions include, but are not limited to: a) Whether the Defendants conspired to violate RICO in the marketing and dissemination of prescription opioids; b) Whether Defendants were, or reasonably should have been, aware that prescription opioids were highly addictive, not proper for long-term treatment, were being over-prescribed, and were causing an addiction epidemic leading to addiction, joblessness, homelessness, and death among users; c) Whether Defendants were, or reasonably should have been, aware that use of prescription opioids in pregnant women leads to Neonatal Abstinence Syndrome (NAS), and children born with NAS exhibit higher rates of behavioral and emotional disorders and cognitive disabilities, necessitating special education services; d) Whether children born to opioid-addicted parents disproportionately require and qualify for enhanced educational services, including special education services; e) Whether Defendants misrepresented that prescription opioids were not highly addictive and were in fact proper for long term use; f) Whether Defendants took reasonable steps to warn doctors, pharmacists, pregnant women, and the public of the highly addictive qualities of prescription opioids and the potentially catastrophic results of opioid use during pregnancy; g) Whether Defendants were negligent.

578. Plaintiff's claims are typical of the claims of other class members in that it has experienced a measurable increase in rates of 1) opioid-related learning disabilities among

[311] School Districts by State 1952-2012, http://proximityone.com/sdstate.htm.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 184 of 214. PageID #: 184

children of opioid-addicted parents for whom it is required to provide enhanced education and services, including under the Americans with Disabilities in Education Act, Section 504 of the Rehabilitation Act of 1973, and Family Education and Privacy Rights Act to provide special education resources; 2) addiction among employees for whom it provides healthcare; 3) addiction among students, for whom it provides counseling, special education, and crisis intervention.

579. Plaintiff will fairly and adequately represent and protect the interests of the class. It has retained experienced and accomplished counsel who are able and prepared to expend the resources necessary to litigate this case. A class action is superior to other methods for fairly and efficiently adjudicating this controversy. Alternatively, class-wide liability under the theories advanced in this complaint could properly be certified under Rule 23(c)(4).

VI. LEGAL CAUSES OF ACTION.

COUNT I: VIOLATION OF RACKETEER INFLUENCED CORRUPT ORGANIZATIONS ACT (18 U.S.C. § 1962-(c) –(d)) (Against all Defendants)

580. Count I is brought by Plaintiff on behalf of itself and the Nationwide and Illinois Classes.

581. Plaintiff incorporates herein by reference all of the allegations in this complaint.

582. At all relevant times, defendants have been "person[s]" under 18 U.S.C. §1961(3) because they are capable of holding, and do hold, a "legal or beneficial interest in property."

583. RICO makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 185 of 214. PageID #: 185

584. RICO makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

585. As alleged herein, at all relevant times, defendants moved aggressively to capture a large portion of the opioid sales market. In so doing, the Manufacturing Defendants launched an aggressive nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain and everyday use; (c) abuse resistant or deterrent; and/or (d) safe and effective for other types of pain for which the drugs were not approved. All defendants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids.

586. In particular, defendants, along with other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (the "Opioid Fraud Enterprise"), whose purpose was to deceive opioid prescribers, the public and regulators into believing that: (a) opioids were safe and effective for the treatment of long-term chronic pain; (b) opioids presented minimal risk of addiction; and/or (c) defendants were in compliance with their state and federal reporting obligations. In participating in these enterprises, defendants sought to maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for chronic long-term and other types of pain.

587. As a direct and proximate result of their fraudulent scheme and common course of conduct, defendants were able to extract billions of dollars of profit. As explained in detail below, defendants' years-long misconduct violated 18 U.S.C. §1962(c)-(d).

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 186 of 214. PageID #: 186

A. The Opioid Fraud Enterprise.

588. At all relevant times, defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of 18 U.S.C. §1961(4), because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Fraud Enterprise: (a) existed separately from each of its component entities; (b) existed separately from the pattern of racketeering in which defendants engaged; and (c) constituted an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturing Defendants, the Distributor Defendants, Caremark, pharmacies, employees and agents of the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

589. Within the Opioid Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The Opioid Fraud Enterprise used this common communication network for the purpose of deceptively marketing, selling and distributing opioids to the general public. When their products, sales, distributions and failure to report suspicious sales were contested by other parties, the Opioid Fraud Enterprise members took action to hide the scheme to continue its existence.

590. The participants in the Opioid Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and the continuing coordination of activities. Through the Opioid Fraud Enterprise, defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing revenues and market share and minimizing their losses. Each member of the Opioid Fraud Enterprise reaped the bounty generated by the enterprise by sharing the benefit derived

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 187 of 214. PageID #: 187

from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers and by failing to report suspicious sales.

591. The Opioid Fraud Enterprise engaged in and continues to engage in deceptive marketing of opioids as non-addictive, and as safe and effective for chronic long-term pain and for uses that are not FDA-approved. Further, the Opioid Fraud Enterprise continues to not report suspicious sales. The Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids. To fulfill this purpose, the Opioid Fraud Enterprise has advocated for, and caused the over- prescription and over-distribution of, opioids by marketing, promoting, advertising and selling opioids throughout the country and across state boundaries and by failing to report suspicious sales. Their receipt of monies from these activities has consequentially affected interstate and foreign commerce. The Opioid Fraud Enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. §1961(5).

592. The Opioid Fraud Enterprise functioned by marketing, selling and distributing opioids to independent public schools, states, counties, other municipalities, doctors, healthcare organizations, pharmacies and the consuming public, while failing to report suspicious sales. Through their illegal enterprise, defendants as co- conspirators engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue for defendants and the other entities and individuals associated in fact with the Opioid Fraud Enterprise's activities through the deceptive marketing and sale of opioids and the failure to report suspicious sales.

593. Defendants participated in operating and managing the Opioid Fraud Enterprise by directing its affairs as described in this complaint. While defendants participated in, and are members of, the Opioid Fraud Enterprise, they have a separate existence from the Opioid Fraud

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 188 of 214. PageID #: 188

Enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

594. Each member of the Opioid Fraud Enterprise furthered the ends of the Opioid Fraud Enterprise through the acts and omissions pled in this complaint.

595. Each Manufacturing Defendant relentlessly promoted opioids to prescribers, regulators and the public as having little to no risk of addiction, and as being safe and effective for the treatment of chronic, long-term pain and other common, everyday uses. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through, and in collaboration with, the pain foundations – a formidable partnership that marketed to hundreds of thousands of prescribers across the country, including prescribers in Chicago and throughout Illinois. The relationship was strengthened, in part, by individuals, including physicians, that held different leadership roles at different times across the various entities participating in the Opioid Fraud Enterprise over the years.

596. On numerous occasions, the Manufacturing Defendants funded the pain foundations' marketing efforts. The Manufacturing Defendants specifically chose to partner with the pain foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third-party sources.

597. Furthermore, all defendants knowingly failed to design and operate a system to monitor suspicious orders of controlled substances and failed to notify the appropriate DEA field division offices in their areas of suspicious orders, including "orders of unusual size, orders

deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

598. The members of the Opioid Fraud Enterprise worked together to further the enterprise by the following manner and means:

(a) jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic long-term pain;

(b) concealing the addictive qualities and risks of opioids from prescribers and the public;

(c) misleading the public about the addictive nature, safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling and/or distributing opioids;

(f) collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective; and/or

(g) failing to report suspicious sales as required by the CSA.

599. To achieve their common goals, defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic and other types of pain as described herein. Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids.

600. The foregoing allegations support that defendants were part of an association of entities that shared a common purpose, had relationships across various members of the Opioid Fraud Enterprise and collaborated to further the goals of the Opioid Fraud Enterprise for a continuous period of time. The Manufacturing Defendants knowingly and intentionally engaged in deceptive marketing practices and incentivized pain foundations, marketing firms and

physicians to do so as well. Defendants knowingly and intentionally failed to report suspicious orders as required by state and federal law and defendants inundated the market with opioids.

B. Mail and Wire Fraud.

601. To attempt to carry out and to carry out the scheme to defraud, defendants, each of whom is a person associated in fact with the Opioid Fraud Enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Fraud Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c). And defendants employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud).

602. Specifically, defendants have committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343) within the past four years. The multiple acts of racketeering activity which defendants committed, or aided and abetted in the commission of, were related to each other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by defendants' regular use of the facilities, services, distribution channels and employees of the Opioid Fraud Enterprise. Defendants participated in the scheme to defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign commerce.

603. In devising and executing the illegal scheme, defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers and the public to obtain money from Plaintiff and the Class by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

604. Defendants' predicate acts of racketeering, 18 U.S.C. §1961(1), include:

(a) Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on misrepresentations and false pretenses, promises and omissions.

605. Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials, the filling of suspicious orders, and the misleading of regulators and the public as to defendants' compliance with state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled and regulators would have not been misled but for defendants' illegal scheme, including:

(a) the FSMB's publication of opioid prescribing guidelines titled, "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

(b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) failing to report suspicious orders as required by state and federal law;

(h) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(i) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(j) documents to process and receive payment for opioids, including invoices and receipts;

(k) payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

(l) deposits of proceeds; and

(m) other documents and things, including electronic communications.

606. Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, the Manufacturing Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

607. Defendants also communicated by U.S. mail, by interstate facsimile and by interstate electronic mail with various affiliates, regional offices, divisions, distributors, regulators and other third- party entities in furtherance of the scheme. The mail and wire transmissions described in this complaint were made in furtherance of defendants' scheme and common course of conduct to deceive prescribers, consumers and regulators, oversupply the market and fail to report suspicious sales.

608. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been concealed from Plaintiff, and they cannot be alleged without access to defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the Opioid Fraud Enterprise's activities made the unlawful tactics discussed in this complaint even more deceptive and harmful.

609. The foregoing allegations support that: (a) the Manufacturing Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets; and (b) all defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

C. Conspiracy Allegations.

610. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d) defendants conspired to violate 18 U.S.C. §1962(c), as described in this complaint.

611. Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share and/or minimize losses for defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

612. Indeed, for the conspiracy to succeed, each defendant had to agree to deceptively market, sell and/or distribute opioids while failing to report suspicious sales. The unanimity of the Manufacturing Defendants' marketing tactics and all defendants' failure to report suspicious sales gave credence to their misleading statements and omissions to prescribers, consumers and regulators, and directly caused opioids to inundate the market nationwide, including in Illinois and Chicago.

613. Defendants knew and intended that government regulators, prescribers, consumers and governmental entities would rely on the collective material misrepresentations and omissions made by them and the other Opioid Fraud Enterprise members about opioids and suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by the public.

614. The Manufacturing Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

615. Defendants also knew that by filling, and failing to report, suspicious sales, they would significantly increase their sales and profits.

616. The foregoing illustrates defendants' liability under 18 U.S.C. §1962(d), by engaging in their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

617. As described herein, defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on defendants' misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for defendants. The predicate acts were committed or caused to be committed by defendants through their participation in the Opioid Fraud Enterprise and in furtherance of their fraudulent scheme.

618. As alleged in this complaint, scores of insurers, prescribers, and consumers, including Plaintiff, relied on defendants' representations and omissions.

619. Plaintiff's and the Class's injuries were directly proximately caused by defendants' racketeering activity. But for defendants' misstatements and omissions – and the scheme employed by the Opioid Fraud Enterprise – Plaintiff and the Class would not have been forced to bear the costs of the current opioid epidemic.

620. As a direct and proximate result of each defendant's conduct and its pattern of racketeering activity, Plaintiff and the Class have been injured.

621. Defendants' violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused injuries and damages to Plaintiff and the Class, and Plaintiff and the Class are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees in accordance with 18 U.S.C. §1964(c).

COUNT II: PUBLIC NUISANCE (Against all Defendants)

622. Count II is brought by Plaintiff on behalf of itself and the Nationwide and Illinois Classes.

623. Plaintiff incorporates, by reference, all other paragraphs of this Complaint, as if fully set forth herein, and further alleges, as follows.

624. Defendants' unlawful actions have created a public nuisance under the laws of all fifty states, including Illinois.

625. Plaintiff alleges that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance.

626. Defendants intentionally, unlawfully, recklessly, and negligently manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to the

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 196 of 214. PageID #: 196

employees and parents and students of CPS of and the members of the Class, resulting in addiction and abuse, an elevated level of crime, death and injuries to residents nationwide, a higher level of fear, discomfort, and inconvenience to the residents and employees of Plaintiff's and the Class's school districts, and direct costs to Plaintiff and the Class.

627. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct is illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

628. Defendants' conduct in unlawfully distributing and selling prescription opioids, or causing such opioids to be distributed and sold, when Defendants knew, or reasonably should have known, such opioids will be diverted, possessed, and/or used unlawfully nationwide, including in and around Plaintiff's school district, damaged Plaintiff and the Class.

629. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

630. Defendants' distribution of opioids while failing to maintain effective controls against diversion was prohibited by federal law.

631. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be unlawfully distributed and possessed nationwide, including in Plaintiff's school district and those of the Class members, will be diverted, leading to abuse, addiction, crime, public health costs, and lasting damage to the mental and emotional health of children born of opioid-addicted parents.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 197 of 214. PageID #: 197

632. Because of the continued use and addiction caused by these unlawfully distributed opioids, the public will continue to fear for its health, safety, and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

633. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety, and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

634. Defendants are aware, or should be aware, of the unreasonable interference that their conduct has caused for the Plaintiff and the Class and are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law.

635. Defendants' conduct in marketing, distributing, and selling prescription opioids, which the Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medically appropriate use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents of Plaintiff's and the Class's school districts and otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with the public's, Plaintiff's, and the Class's right to be free from disturbance and reasonable apprehension of danger to person and property.

636. It is reasonably foreseeable to the Defendants that their conduct will cause deaths and injuries to the students and staff of Plaintiff and the Class, and will otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with the public's, Plaintiff's, and the Class's right to be free from disturbance and reasonable apprehension of danger to person and property.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 198 of 214. PageID #: 198

637. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes not only causes deaths and injuries, but also creates a palpable climate of fear among students, parents and staff of Plaintiff's and the Class's school districts where opioid diversion, abuse, and addiction are present, and where diverted opioids tend to be used frequently.

638. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries, and make Plaintiff's and the Class's school districts safer places to work and receive an education.

639. Defendants' conduct is a direct and proximate cause of injuries to the Class and Chicago Public Schools, and costs borne by Chicago Public Schools and the members of the Class for increased special education needs, and a significant and unreasonable interference with health, safety, and welfare, and with CPS's and the class's right to be free from disturbance and reasonable apprehension of danger to person and property.

640. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the students and staff of the Plaintiff's and the Class's school districts, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff and the Class have a clearly ascertainable right to abate conduct that perpetuates this nuisance.

641. Defendants created this nuisance of the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create. However, Defendants intentionally and/or unlawfully failed to maintain effective controls against

diversion through proper monitoring, reporting, and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship, and failed to halt, suspicious orders of opioids, and/or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

642. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that, where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, the opioids would be diverted and create an opioid abuse nuisance nationwide, including in and around Plaintiff's and the Class's school districts.

643. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

644. As a direct result of Defendants' conduct, Plaintiff and the Class have suffered actual injury and damages, including, but not limited to, significant expenses for health services, health insurance, disability payments, other services, special education programs, increased security, loss of tax revenue, costs related to opioid addiction treatment and overdose prevention, and costs associated with educating students born with NAS.

645. Plaintiff and the Class further seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions.

646. The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gatekeeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to Plaintiff and the Class.

647. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*: injunctive relief; restitution; disgorgement of profits; compensatory, treble, and punitive damages; all damages allowed by law to be paid by the Defendants; attorney's fees and costs; and pre- and post-judgment interest.

COUNT III: ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT (Against All Defendants)

648. Count III is brought by Plaintiff on behalf of itself and the Illinois Class against the Manufacturing Defendants.

649. Plaintiff restates and realleges, and incorporates herein, the preceding paragraphs as if fully set forth herein.

650. At all relevant times, the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") provided causes of action for:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission or such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act," approved August 5,

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 201 of 214. PageID #: 201

> 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. 815 ILCS 505/2.

651. Pursuant to ICFA, Manufacturing Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacturing, promotion, and sale of prescription opioids to individuals in and around Plaintiff's and the Class's school districts.

652. Manufacturing Defendants intended that individuals in Plaintiff's and the Class's school districts rely on their materially deceptive practices and purchase prescription opioids as a consequence of the deceptive practices, including Manufacturing Defendant's misrepresentations and omissions of material fact with respect to the harmful, addictive, and deadly qualities of prescription opioids.

653. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused the opioid epidemic plaguing Plaintiff's community. Each Defendant has a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

654. The Defendants also omitted material facts in their representations about themselves and their action, causing confusion or misunderstanding as to approval or certification of goods or services.

655. As alleged herein, Defendants wrongfully represented the benefits, safety, and effectiveness of prescription opioids.

656. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiff and the Illinois Class.

657. Defendants' unfair practices include targeting vulnerable populations and lay audiences for campaigns of misinformation and oppressive marketing; disseminating deliberately

false, unproven and misleading marketing in violation of state and federal law; promoting the use and sale of opioids over safer and more effective drugs without any medical or scientific basis; and rigging the medical and health insurance reimbursement system to maximize the availability of opioids for abuse, while stifling alternatives to prevent competition, to the grave detriment of society and Plaintiff.

658. These unfair practices offend Illinois public policy, as articulated by the Illinois General Assembly opposed to the Illinois Controlled Substances Act to combat “the rising incidence in the abuse of drugs and other dangerous substances” that leads to “damage to the peace, health, and welfare of the citizens of Illinois,” 720 ILCS 570/100, and public policies against fraud and for the protection of consumers. As the General Assembly has concluded, “drug addiction [is] among the most serious health problems facing the people of the State of Illinois.” 745 ILCS 35/2. Defendants also worked to undermine public policy as articulated by regulations contained in state and federal law that try to ensure the honest marketing and safe and appropriate use of pharmaceutical drugs.

659. These practices, especially the misinformation and promotion of abuse of opioids, are immoral, unethical, oppressive and unscrupulous. Patients and medical providers, without access to Defendants’ medical and scientific information, must rely on the statements and actions of Defendants and could not avoid the campaign of misinformation and lies perpetrated by Defendants over years. Patients and Plaintiff were swamped by Defendants’ regulatory and marketing campaign, coupled with the vast oversupplies of opioids by distributors. Defendants’ actions tainted the scientific, medical, and regulatory communities to the extent that the opioid addiction and related harms could not reasonably be avoided.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 203 of 214. PageID #: 203

660. The harms caused by Defendants' unfair and deceptive practices, including opioid abuse, addiction, overdose and death, compounded by the human cost of those afflicted with opioid addiction and the financial toll on the healthcare system, including Plaintiff, are not outweighed by any benefits to consumers or competition. No one—except Defendants—benefits from a marketplace or healthcare system plagued by deception and misinformation, or from the over-prescription of opioids and related problems.

661. Defendants have made and/or disseminated deceptive statements and/or caused to be made or disseminated deceptive statements, including but not limited to the following:

- Creating, sponsoring, and assisting the distribution of patient education materials distributed to consumers nationwide that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing materials to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff nationwide, including in Illinois and Chicago, while purportedly educating them on new pain standards; and

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers, including in Illinois and Chicago, through in-person detailing.

662. Had it not been for Defendants' deceptive statements, Plaintiff and the Illinois Class would not have made payments to cover its employees' off-label use of Defendants' drugs.

663. As a result, Plaintiffs and the Illinois Class have suffered an ascertainable loss, in an amount to be determined at trial.

COUNT IV: NEGLIGENCE: GENERAL DUTY OF CARE (All Defendants)

664. Plaintiff incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

665. Count IV is brought by Plaintiff on behalf of itself and the members of the Nationwide and Illinois Classes against all of the Defendants.

666. The Restatement (3rd) of Torts, § 7 recognizes a duty to exercise reasonable care "when the actor's conduct creates a risk of physical harm."

667. Defendants, collectively, manufactured, marketing, and disseminated highly dangerous and addictive prescription drugs, which creates a risk of physical harm.

668. Defendants, collectively, acted to expand the market for opioids to the treatment of chronic pain.

669. In doing so, Defendants failed to act with reasonable care in the manufacturing, marketing, promoting, selling, and/or distributing opioids for the treatment of chronic pain.

670. Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels. And Defendants knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

671. Nonetheless, Defendants persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids and making opioids readily available to consumers without regard to the likely harm they would cause.

672. Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

673. Defendants' conduct directly injured Plaintiff. Defendants' conduct caused Plaintiff to pay for or otherwise reimburse the cost of countless unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated with opioid addiction and abuse among their insureds, whom Manufacturing Defendants specifically targeted with their marketing schemes.

674. Defendants knew of or should have known of the foreseeable injuries to Plaintiff caused by their failure to act with reasonable care. Defendants were aware that their goal of significantly expanding the marketplace for opioids depended in part on comprehensive coverage of opioids by insurers and third-party payors. Defendants also knew that their goal of increasing

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 206 of 214. PageID #: 206

profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for unnecessary and inappropriate opioid prescriptions to treat chronic pain and the health services and expenditures associated with the opioid epidemic for health care payors, such as Plaintiff.

675. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering damages.

COUNT V: NEGLIGENCE: VIOLATION OF STATUTORY DUTIES
(Against All Defendants)

676. Count V is brought by Plaintiff on behalf of itself and of the Nationwide and Illinois Classes.

677. Plaintiff incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

678. Reasonably prudent prescription opioid manufacturers and distributors would not have misrepresented the risks of prescription opioids, nor overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing. Reasonably prudent prescription opioid manufacturers and distributors would have implemented basic controls—required under federal and Illinois law—to prevent opioid diversion in the supply chain.

679. Instead, Defendants systematically and fraudulently violated their statutory duties related to marketing controlled substances, and duties to maintain effective controls against the diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Defendants failed to meet the standard of care established by statute by looking the other way

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 207 of 214. PageID #: 207

while massive quantities of prescription opioids flowed to Plaintiff's insureds. *See, e.g.*, the Controlled Substances Act, 21 U.S.C. § 801 et seq; 21 C.F.R. § 1301.74(b).

680. Every registrant—including each Defendant—is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes.[312] Specifically, drug manufacturers and distributors are required to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[313]

681. As such, Defendants breached their duties to exercise due care in the business of manufacturing, marketing, and wholesale distribution of prescription opioids, including by filling unreasonably suspect orders over and over again, without imposing basic controls to monitor, identify, investigate, limit, and report suspicious orders for opioids. The very purpose of these duties was to prevent the harms that have directly followed: diversion of highly addictive drugs for illegal and/or non-approved purposes. Thus, the causal connection between Manufacturing and Distributor Defendants' conduct and the ensuing harm was entirely foreseeable.

682. Accordingly, Defendants breached their statutory and regulatorily established duties of care, designed specifically to prevent the harms from the abuse and misuse of controlled substances, including opioids, by engaging in negligence *per se*, to the significant harm of Plaintiff and its members.

683. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering damages.

[312] *See* 21 U.S.C. § 823(e).
[313] *Id*. at § 823(b)(1); *see also id.* at § 823(a)(1).

COUNT VI: NEGLIGENCE: COMMON LAW FAILURE TO WARN
(Against Manufacturing Defendants)

684. Court VI is brought by Plaintiff on behalf of itself and the National and Illinois Classes against the Manufacturing Defendants.

685. Plaintiff incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

686. Manufacturing Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Manufacturing Defendants had such actual and unequal knowledge of the risks and harms likely to result from the long-term prescription and knew or should have known that harm would result from such use.

687. To expand the market for opioids, however, Manufacturing Defendants engaged in a misinformation campaign to alter public perception of opioids, and deceive doctors, federal regulators, and the public about their addictive and unsafe qualities. Manufacturing Defendants perpetrated virtually uniform misrepresentations, concealments, and material omissions regarding (a) the safety and efficacy of opioids for the treatment of chronic pain and (b) their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

688. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturing Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks.

Case: 1:19-op-46042-DAP Doc #: 1 Filed: 11/20/19 209 of 214. PageID #: 209

689. Accordingly, Manufacturing Defendants spent millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

690. Manufacturing Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable, though providing such warnings and accurate information would not have imposed a burden. Rather, each Manufacturing Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

691. Manufacturing Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

692. Plaintiff and the Class thus, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, Plaintiff and the Class, as well as other third-party payors and members of the medical community and public, were obligated to rely on Defendants' representations about opioids. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

693. Manufacturing Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels, including through their financial incentives and information sharing arrangements with other Defendants. Manufacturing Defendants also knew

that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

694. Manufacturing Defendants further knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their friends, families, and communities, and those, like Plaintiff, responsible for paying for health care costs associated with opioid addiction and abuse among their insureds and providing services, including federally-mandated special education, to children born to and/or living with opioid-addicted parents or guardians.

695. Nonetheless, Manufacturing Defendants unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. In doing so, Manufacturing Defendants failed to take reasonable precautions in presenting opioids to the public.

696. By failing to adequately warn the public, including prescribing doctors, Plaintiff, and the Class of the dangers of opioids, Manufacturing Defendants' conduct directly injured Plaintiff and the Class. Because of Manufacturing Defendants' misinformation campaign, Plaintiff and the Class paid for or otherwise reimbursed the cost of countless unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated with opioid addiction and abuse among their insureds, whom Manufacturing Defendants' specifically targeted with their marketing schemes.

697. As a consequence of the Manufacturing Defendants' breach of their common law duty to warn, Plaintiff and the Class has suffered damages and will continue to suffer damages.

VII. DAMAGES.

698. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and the Class injury, because Plaintiff and the Class

paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference. Plaintiff's and the Class's injuries were directly and/or proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff and the Class would not have paid the health services and expenditures required to treat, respond to, and otherwise handle opiate-related incidents and opiate-related deaths. Plaintiff and the Class were most directly harmed, and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here. Plaintiff and the Class seek all legal and equitable relief, as allowed by law, including, *inter alia*: actual damages (as described above in language expressly incorporated herein by reference); treble damages; equitable relief; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

699. Defendants' intentional and/or unlawful conduct, as described herein, resulted in direct and foreseeable, past and continuing, economic damages, which Plaintiff and the Class have incurred and continue to incur, including: (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs associated with increased healthcare and healthcare insurance; (c) costs regarding disability payments; (d) costs associated with special education means, including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling due to opioid-related family crisis; (e) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; (f) costs associated with increased school security in all facilities of the school board district; (g) loss of tax revenue; and (h) treble damages, and for which Plaintiff seeks relief as to all claims and counts, as alleged

herein. Plaintiff also seeks the means to abate the epidemic (created by Defendants' wrongful and/or unlawful conduct), including but not limited to, economic damages from the Defendants as reimbursement for the costs associated with past, present, and future efforts to address, pay for, and/or eliminate the aforementioned hazards to public health and safety.

700. Plaintiff has incurred and seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions, including all counts alleged against Defendants. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

701. Other than such damages specifically disavowed herein, Plaintiff seeks all legal and equitable relief, as allowed by law (for all counts alleged against Defendants), including, *inter alia*: injunctive relief; restitution; disgorgement of profits; compensatory, treble, and punitive damages; all damages allowed by law to be paid by the Defendants; attorney's fees and costs; and pre- and post-judgment interest.

VIII. PRAYER FOR RELIEF.

WHEREFORE, Plaintiff prays that summons be issued notifying Defendants of this Complaint, and that after all legal delays, Defendants be required to answer same, and after all proceedings and a jury trial, there be a judgment in favor of Plaintiff for all amounts commensurate with Plaintiff's damages, including but not limited to:

(1) past, present, and future costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) past, present, and future costs associated with increased healthcare and healthcare insurance; (3) past, present, and future costs regarding disability payments; (4) past, present, and future costs associated with increased

educational services, including but not limited to special education needs, including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling due to opioid-related family crisis; (5) past, present, and future costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; (6) past, present, and future costs associated with increased school security in all facilities of the school board district; (7) loss of tax revenue; (8) disgorgement of Defendants' unjust enrichment; (9) all costs and means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct; (10) treble damages; (11) all other costs and damages specified herein; (12) attorneys' fees, costs, and expenses of suit; (13) pre- and post-judgment interest; and (14) such other relief as the Court deems appropriate.

For the RICO violations, an award of trebled damages as consistent with 18 U.S.C. § 1964(c) compensatory and actual damages, reasonable attorney's fees, pre-judgment interest, post-judgement interest, and costs against Defendants, each and every one of them jointly and severally, and any additional amount that this Court deems just and proper.

Plaintiff further demands a jury trial on all issues so triable.

Date: November 20, 2019

Respectfully submitted,

/s/ Cyrus Mehri
One of the Attorneys for Plaintiff

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